UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	
Plaintiff,	)	
	)	Criminal Action
v.	)	No. 09-10330-GAO
STRYKER BIOTECH, LLC, et al.,	)	
Defendants.	)	

BEFORE THE HONORABLE GEORGE A. O'TOOLE, JR.
UNITED STATES DISTRICT JUDGE

DAY FOUR
JURY TRIAL

John J. Moakley United States Courthouse
Courtroom No. 9
One Courthouse Way
Boston, Massachusetts 02210
Thursday, January 12, 2012
9:07 a.m.

Marcia G. Patrisso, RMR, CRR
Official Court Reporter
Kimberly A. Smith, RDR, CRR
John J. Moakley U.S. Courthouse
One Courthouse Way, Room 3510
Boston, Massachusetts 02210
(617) 737-8728

Mechanical Steno - Computer-Aided Transcript

APPEARANCES:

OFFICE OF THE UNITED STATES ATTORNEY
By: Jeremy M. Sternberg, Susan B. Winkler, and
Gregory F. Noonan, Assistant U.S. Attorneys
John Joseph Moakley Federal Courthouse
Suite 9200
Boston, Massachusetts 02210
On Behalf of the Government

ROPES & GRAY
By: Brien T. O'Connor, Esq.
Joshua S. Levy, Esq.
Aaron M. Katz, Esq.
Cori A. Lable, Esq.
Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199-3600
On Behalf of the Defendant Stryker Biotech, LLC

NUTTER, McCLENNEN & FISH, LLP
By: Robert L. Ullmann, Esq.
Maya L. Sethi, Esq.
Seaport West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
On Behalf of the Defendant William Heppner

WILMER CUTLER PICKERING HALE & DORR, LLP
By: Brent J. Gurney, Esq.
Miranda Hooker, Esq.
1875 Pennsylvania Avenue
Washington, D.C. 20006
On Behalf of the Defendant David Ard

LIBBY HOOPES, P.C.
By: Frank A. Libby, Jr.
Alathea E. Porter, Esq.
175 Federal Street
Boston, Massachusetts 02110
On Behalf of the Defendant Jeffrey Whitaker

I N D E X

(The following proceedings were held in open court before the Honorable George A. O'Toole, Jr., United States District Judge, United States District Court, District of Massachusetts, at the John J. Moakley United States Courthouse, One Courthouse Way, Boston, Massachusetts, on January 12, 2012.

The defendants, William Heppner, David Ard and Jeffrey Whitaker, are present with counsel. Assistant U.S. Attorneys Jeremy Sternberg, Susan Winkler and Gregory Noonan are present.)

THE CLERK: All rise.

(The Court enters the courtroom at 9:07 a.m.)

THE CLERK: For a continuation of the Stryker Biotech trial. Please be seated.

THE COURT: Good morning. The clerk said Mr. Ullmann had something before we call up the jury.

MR. ULLMANN: Yes. Very briefly, your Honor. We're not asking for a ruling at the time, but the defendants are intending to file a motion to exclude the testimony of newly identified IRB witnesses, representatives of institutional review boards, including two who are on the government's witness list. These were identified for the first time in late December. They represent a dramatic shift in the government's theory of items case. Suddenly, IRBs were alleged to be victims of the conspiracy, not just surgeons and the FDA.

And for that reason, if the government mentions any

IRB witness in its opening, it does so at its peril.

THE COURT: Okay. Ms. Winkler?

MS. WINKLER: Your Honor, I don't think we'll have an issue. But one thing I would like to raise is we have an objection to one of the demonstrative exhibits the Defendant Ard intends to use because it's post-conspiracy. It includes data from the summary exhibit. And we could deal with it later if you would like.

THE COURT: Well, is it going to be used in the opening?

MR. GURNEY: Yes, your Honor.

THE COURT: Then I don't think we should deal with it later.

MS. WINKLER: The problem with the exhibit is it deals with data from '04 to '09, post-conspiracy, and discusses -- you know, it includes underlying data that is beyond the data of the conspiracy and sales data beyond the date of conspiracy; and in line with some of the discussions and positions taken by the defense with regard to the government's evidence, we think it's unfair that they be able to go beyond conspiracy if the government's not allowed to.

THE COURT: Whose exhibit is it, yours, Mr. Gurney?

MR. GURNEY: It's my exhibit, your Honor.

Your Honor, the chart is a chart of adverse event data. We wanted to be complete so we're not accused of

cherry-picking. So it includes all data that is available. Although some of the reports actually happened outside the conspiracy, most of the actual events happened inside the conspiracy period just so they get reported later. But for purposes of talking about what is the adverse event rate on the products, we wanted to be complete so the government doesn't turn around and say we have selectively presented the data with respect to the percentage of adverse events.

THE COURT: May I see the exhibit?

MR. O'CONNOR: Your Honor, if I may add one thing to that. We have said several times what the incidence of adverse events was and how many surgeries there were, and the government has not objected. We've been putting in -- 63, I think, is what we said out of 10,000. They haven't objected.

THE COURT: This reflects those numbers?

MR. O'CONNOR: This reflects that.

THE COURT: And what's the underlying source of the data?

MR. O'CONNOR: Your Honor, it's company records. It's information that's going to be introduced.

And with respect to the number, just to be clear, you know, it is -- it does include all adverse events that were reported by the 2009 year. Virtually all of the 63 happened, you know, within the -- by '08. I can't tell you right now because we've been very precise about how many, but we did go

beyond the conspiracy period for some. But we've been saying to them all along, and they have not objected, in our very important adverse event motion to you, 63 out of 10,000. And that's what's in our opening as well as in that. So I just want to be very clear about that.

THE COURT: There was another rate.

MR. O'CONNOR: Yup.

THE COURT: That was adverse events from something else, Calstrux alone or something like that?

MR. O'CONNOR: No, your Honor.

THE COURT: That was 12 per 15,000 or something like that?

MR. O'CONNOR: Somewhere we have mentioned, you know, is the incidence of adverse events greater with Calstrux when it's not with OP-1 as compared to the incidence of adverse events with the combination? So it may be that is the first point you're thinking about. We don't intend to mention that.

THE COURT: There was a different sum of uses. I think it was around 15,000. And I don't remember the numbers precisely but --

MR. O'CONNOR: Ms. Lable has it.

THE COURT: -- my point is that to the extent there is -- that might be a point the government might want to make, I'm not sure, but my question really was about this current controversy, whether if there are other numbers supporting

other rates of other uses, do they likewise cover the same period? That was my question.

MR. O'CONNOR: That's a good question. We're not going to mention --

THE COURT: No, but they might.

MR. O'CONNOR: Well, at least in our opening, any -- we're not going to do a comparative. We're just going to say the incidence of adverse events is 63 out of 10,000. I was going to say that's about one half of 1 percent, just so the Court knows. I'm not going to compare it to anything else. And I don't think Mr. Ard's counsel, Mr. Gurney, is intending on doing that either.

MR. GURNEY: No. That's correct.

THE COURT: Ms. Winkler?

MS. WINKLER: Your Honor, it's true they've mentioned these numbers. We've viewed it as an evidentiary issue that would come up during trial, obviously. But the data that has been provided, some of it does go beyond -- I mean, some of the adverse events were post conspiracy that they've included in this data. I don't see how -- and the reason that those MDRs were filed at the time they were is because the FDA went in, found out in the 483 they didn't want us to talk about yesterday -- found out they hadn't filed them and told them to file them, which is why they came in later.

THE COURT: Well, I guess I think this: If the data

is -- of course, the reliability of the underlying data is fair game for questioning on cross-examination. So assuming for a moment reliability, as a counting matter, the rate is perhaps informative about qualities of the combination more than it is about the actions of the defendants; that is, if it's accurate, it's arguably objective as opposed to characterizing behavior as lawful or unlawful. Therefore, I don't think the overlap -- exceeding the scope of the behavioral allegations of the indictment matters that much.

So I guess I would permit it on my current limited understanding of what this is, and it's subject to attack and criticism in the course, okay?

MR. O'CONNOR: Thank you.

THE COURT: All right. So if we're ready for the jury, we'll bring them out and swear them, of course. I will have some introductory instructions which will take a few minutes. Then we'll have the government. We'll see how time goes on this.

If it's the government for about an hour and then Stryker for about an hour or a little more, we're going to be projecting more towards 11:30 for a time of a break, but I'd rather not interrupt anybody. So unless the government is going to be --

MS. WINKLER: I think ours may be a little bit shorter.

MR. O'CONNOR: As I said, outside 75 minutes but --
THE COURT: All right. We'll see how it goes. So we'll probably take a break after Stryker. And the order for the others were?
MR. ULLMANN: Mr. Heppner will go next.
THE COURT: Heppner, Ard and then Whitaker. Is that it?
Okay. Let's get the jury.
THE CLERK: Yes, sir.
THE COURT: Now, I understand also at least some of you are going to be using the electronic presentation devices during openings. Is that correct or not?
MS. WINKLER: Not the government, your Honor.
THE COURT: The government is not.
MR. O'CONNOR: I'm sorry. I missed the question, your Honor.
THE COURT: Whether you're using the electronic presentation.
MR. O'CONNOR: Yes, your Honor. And we're also going to put a board up here briefly.
THE COURT: I want to make sure the feed is active when you need it, that's all.
MR. O'CONNOR: Yes.
THE COURT: It will be through a computer?
MR. O'CONNOR: Yeah. I'll be looking here and -- yes.

THE COURT: And I understand I can leave it on one setting and it will be toggled between government and defense, or is it all one database?

MS. WINKLER: It's all for the defendants today. It will be toggled, but we don't need it.

THE COURT: But when it happens it will be toggled, is that it? Because normally -- normally -- in the past I've had to switch back and forth between feeds. But I can just leave it set on one feed, is that it? Okay.

(Pause.)

THE CLERK: All rise for the jury.

(The jury enters the courtroom at 9:18 a.m.)

THE CLERK: Will the jurors remain standing; everyone else be seated, please.

(The jury is duly sworn.)

THE CLERK: Please be seated.

THE COURT: Good morning, jurors.

THE JURORS: Good morning.

THE COURT: With the administration of the oath of office as jurors, you're now officially a jury and the trial has officially begun. We were working towards this moment the first part of the week. We appreciate your patience again, and we're ready to present the trial and its evidence to you for your judgment.

Let me just make a few introductory remarks about how

we're going to proceed, what the trial will look like in terms of procedure and form and so on, and then we'll hear from the lawyers to begin presenting the case.

As I'm sure you can appreciate, of course, this is a very important occasion for the parties to this trial. For both sides. For both the government and for the defendants. This is something they've been anticipating for some time and working toward and preparing for. And it is a very important event for all involved, and we're sure you will treat it with that sense of importance and significance.

A trial is also a very formal matter. We proceed in accordance with rules of procedure that have been established for these purposes. Some of the rules are rather ancient, some are relatively new, but they govern the manner in which the case will be presented to you. And the reason we follow rules of procedure like this is not just because that's what lawyers do, but because it is the judgment of experience that following these procedures will help to present the evidence fairly so that you can make a sensible and fair judgment on the evidence.

A consequence of formality is that sometimes things will be a little bit stiff, perhaps even somewhat inefficient at times. We will do our best to be as efficient as we possibly can, but efficiency is a secondary goal to doing justice. And we hope you understand that. So it may be necessary, for example -- it's common in trials like this --

for us to take out some time for the lawyers and I to resolve some legal issues or procedural matters. And we'll have to ask you to stand aside while we do that. Please understand that all of that is working towards completion of the trial. And as I say, we'll try to do it as efficiently as possible, but sometimes it will be necessary to make some interruptions.

Another part of the formality is we have a set sequence of events that make up the parts of the trial. When I finish this brief introduction we'll have the first part, and that's the lawyers' opportunity to make what we call "opening statements." The lawyers get to address you -- and you'll see there's a little stand right in front of you here where they'll stand in front of you -- and present what they expect you will hear in the course of the presentation of the evidence. In other words, lawyers for all the parties get a chance to summarize what they think the evidence is going to show as you hear it over the course of the trial.

The opening statements themselves are not part of the evidence; they're a summary of what is expected. And what actually is admitted may coincide exactly with what's predicted or may vary in various respects. The evidence you'll hear, of course, will be what's presented by the witnesses and not by the lawyers and their statements. But the statements are useful because they will introduce you to the issues in the case and prepare you to hear the evidence so that you're not

just hearing it cold, as it were. You'll be able to follow the presentation of the evidence a little bit more if you've heard an overview summary.

I like to tell jurors you can think of it like the picture on the outside of the jigsaw puzzle box. They get to tell you what it's supposed to look like from their point of view when all the pieces have been put together. I expect you'll hear very different pictures because that's customary. That's why we have a controversy. It will be up to you to put the pieces together at the end of the case and see what picture emerges or doesn't emerge from that. But the opening statements may be useful for that.

That's likely to take the bulk of today, to have the opening statements. So as a strict matter, you will not, probably, get any evidence today because the lawyers' statements are not, strictly speaking, evidence, but you will hear an introduction which will give you some context and appreciation of what you're going to hear over the next several days, perhaps weeks, as the evidence is presented.

Now, then, I expect tomorrow we'll begin the formal presentation of the evidence. And as I'm sure you realize, the evidence will come largely through the testimony of witnesses who will come into the courtroom, swear to tell the truth, and then answer questions that are put to them by the lawyers, each lawyer for each party having an opportunity to question each

witness. The witnesses will sit in the witness box right across from you and, as I say, will answer questions.

The question-and-answer format is another part of the formality of the trial. We don't just have people come in, sit there and talk to you and tell you what they think you ought to know; rather, their testimony is guided, in a sense, by the questions that are put to them by the lawyers. And because every lawyer from whatever perspective gets to ask questions, hopefully we get the full perspective brought out through the series of questioning. It's important to remember that it is the witnesses' answers to questions that constitute the evidence. Sometimes questions can be themselves suggestive, but unless the witness says so, you don't have any evidence of that fact.

Another reason for the question-and-answer format, in addition to directing the testimony and, therefore, by the way, making it more efficient because the witnesses won't stray off -- the lawyers will guide them to what's important -- another reason is that in addition to procedural rules, we follow what we call "rules of evidence." And the rules of evidence are a body of legal principles to be applied in cases like this that govern in a general sense the quality of information that is properly the basis for the important judgment that you people will make.

The law makes some usually categorical judgments about

kind of evidence, some being thought more reliable as a general matter, some being thought less reliable as a general matter. And the rules of evidence sort of police those principles and allow in reliable evidence for your consideration and exclude evidence that's thought to be inefficiently reliable as a general matter.

Now, that's not something for you to worry about. You will consider whatever evidence is admitted and you'll decide how reliable it is at the end of the case. But part of the presentation -- you'll see the application of the rules of evidence because the lawyers may ask me for rulings from time to time about whether evidence should be allowed in or not.

You've probably seen this happen. If the lawyer thinks a question calls for evidence that shouldn't be admitted, the lawyer will object to the witness answering the question. I'll then make a ruling as to whether the objection is sound or unsound. If I agree with the objection, I will say something like "sustained" -- I sustained the objection -- and the witness won't answer the question.

If that's the case, don't try to answer the question yourselves. Don't guess at what the answer might have been if the witness had been permitted. Just take it for whatever reason that answer isn't going to be given. The question gives you no evidence. Wait for the next question and the answer given to that.

On the other hand, I might overrule the objection, disagree with it, and the witness will be allowed to go ahead and answer the question. That answer then comes into evidence like all the other answers are given. It doesn't have any special significance because it follows an objection. An objection isn't a hint or a clue that this has got to be important because they wouldn't be objecting otherwise. That's not true for a number of reasons, perhaps the principal one being that the principles that we'll be applying, the lawyers and I, in applying the rules of evidence have nothing to do with the merits of this case. They're just simply entirely separate and general principles, and there's no meaning to be found in a ruling of evidence one way or another for any of the issues in the case. So don't look for any because it's simply not there. If the evidence is given, you'll consider it. If it's not given, you don't have it and you can't consider it.

Most typically I'll understand the nature of the objection from context and make a ruling right away. It may be necessary on occasion for us to allow the lawyers to make a little argument before I rule one way or the other. If that happens we'll go over to the sidebar and I will allow the lawyers to do that. We do it out of your hearing because if you're not going to hear the evidence, we don't want you to have heard the discussion about it before it's ruled on.

Because the acoustics in this room are so good, we

don't want you to be listening in on what we're saying because the point is to do it out of your hearing, and so we will mask, we hope, our conversations by playing a little music. There are speakers behind you. And we hope it's pleasant enough.

(Laughter.)

THE COURT: But if you find that I'm hitting the CD button, don't be surprised. That may happen.

So that's the way that the evidence will be presented through the witnesses. There will not only be testimony of witnesses, there will be exhibits. We have a system now that permits the digitizing of exhibits, and so you will be able to see them on the screens in front of you. And you see in the front row you have monitors? There are monitors in the back row for jurors. There's a console between every other seat or so, and if you lift up the top, you can rotate out the monitor.

You don't have to do it right now. I think it will be used at some point in the morning. If you want to do it now, it's fair enough. The on-off button is in the lower right-hand side. And ultimately, you'll have a system in the jury room where you've seen the monitor on the wall. You'll be able to access all the exhibits through that system.

So the bulk of the time of the case will be the presentation of the evidence. When that's been completed, we'll move to the latter stages. At the end of the case the lawyers will have another opportunity now not to predict what

the evidence will be but to sum it up for you, to try to recall for you what the evidence has been and, of course, ask you respectively to find the evidence in their favor. That's part of their responsibility to their clients.

I'll have some instructions then to tell you about the principles of law that pertain to the charges that are made here about which you'll have to make a judgment, and then you'll conduct your deliberations and render a verdict in the case. So that's the outline we'll follow.

So let me -- before we hear from the lawyers, let me set the stage by reminding you -- I spoke briefly about the nature of the charges that are made by the indictment. Let me outline them again for you so you'll have an understanding of what it is that this indictment charges these particular defendants with having done.

An indictment is the document or the means of making a criminal charge. It's presented by a grand jury. A grand jury is very different from a trial jury. A grand jury doesn't consider guilt or innocence; it considers the adequacy of evidence to think whether it's even plausible that a charge should be made or not. If the grand jury approves of them, the charge can be made. So an indictment is no evidence that anybody has done anything; it simply is the charge itself and proposes the question that will be presented by the evidence at trial.

So in this case the indictment alleges several crimes. I think I told you that there are separate counts in an indictment. Each count alleges a separate offense. So there are a total of 12 counts that will be considered by you ultimately at the end of the case.

The first count is a charge of conspiracy, criminal conspiracy. A statute of the United States, Section 371 of Title 18, provides as follows: "If two or more persons conspire either to commit any offense against the United States or to defraud the United States or any agency thereof in any manner for any purpose, and one or more of such persons do any act to effect the object of the conspiracy" -- that's the end of the quote -- then such persons are guilty of the crime of criminal conspiracy.

Count 1 of this indictment charges that beginning no later than February 2006 and continuing thereafter until in or about February 2008 in the District of Massachusetts and elsewhere, the several defendants knowingly and willfully did combine, conspire, confederate and agree with each other and others known and unknown to the grand jury to defraud the United States and its agency, the Food and Drug Administration, by impeding, impairing, obstructing and defeating through craft, trickery, deceit and dishonest means the lawful function of the FDA to protect the health and safety of the public by ensuring that medical devices marketed and distributed in the

United States were safe and effective for their intended uses. And the indictment further charges that the defendants further conspired to commit wire fraud in violation of another statute of the United States.

The indictment further charges that the objective of the conspiracy was to evade and frustrate efforts by the FDA to regulate the safety and efficacy of Stryker Biotech medical devices, this objective to be achieved through the deliberate manipulation of physicians into using an unapproved and untested mixture of products you will hear about known as OP-1 and Calstrux. You'll hear a good bit about those names. The indictment charges that the deliberate manipulation of physicians was accomplished through illegal promotion of those products.

One of the objectives, as I've just told you, that is alleged to have been an objective of the conspiracy alleged in Count 1 is to commit the crime of wire fraud. Another statute of the United States, Section 1343 of Title 18, provides in relevant part as follows: Whoever having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations or promises -- whoever has done that -- transmits or causes to be transmitted by means of wire, radio or television communication in interstate or foreign commerce any writings, signs, signals, pictures or sounds for the

purpose of executing such scheme or artifice to defraud, commits an offense. So as I said earlier, it prohibits the use of interstate wire communications facilities in execution of an intentional scheme to defraud, in summary.

So Counts 2 through 6 of the indictment allege that beginning on a date unknown, but no later than in or about February 2006, and continuing until at least in or about February 2008, in the District of Massachusetts and elsewhere, the defendants, the company and the several individuals, devised and intended to devise a scheme and artifice to defraud physicians and hospitals, and to obtain money by means of false and fraudulent pretenses, representations and promises concerning material facts and by concealing material facts.

The defendant *[sic]* alleges that the purpose of the scheme or artifice to defraud was for Stryker Biotech to obtain millions of dollars in sales from OP-1 and Calstrux, and to enrich the individual defendants through additional compensation from Stryker Biotech all through the deliberate manipulation of healthcare professionals with false, deceptive, incomplete and misleading information, into using OP-1 in unapproved and untested ways including in a mixture with Calstrux. Each of Counts 2 through 6 alleges a separate particular email, that is, interstate -- alleged to be an interstate wire communication, as constituting the forbidden use of the interstate communications facilities.

Counts 7 through 12 allege what we might, in shorthand, refer to the offense of misbranding a medical device. The Federal Food, Drug and Cosmetic Act includes, among other things, the following relevant provisions: First, the act provides that a drug or medical device subject to regulation by the FDA shall be deemed to be misbranded unless its labeling bears adequate directions for use and adequate warnings against uses that may be dangerous to health.

Second, the act prohibits the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of a drug or device, or the doing of any other act with respect to a drug or device, if such act is done while the article is held for sale after shipment in interstate commerce and results in such article being misbranded in the sense that I previously mentioned.

And third, the act makes it a crime for a person to violate that prohibition against misbranding with an intent to defraud or to mislead.

Counts 7 through 12 of the indictment allege that the company, Stryker Biotech, committed this misbranding offense. Counts 7 through 12 are not addressed to the individual defendants in the case; they are not defendants in those counts.

With respect to the company, the indictment charges that in the District of Massachusetts and elsewhere, Stryker

Biotech, LLC, did, while quantities of OP-1 were held for sale after such devices were shipped in interstate commerce, and with the intent to defraud and mislead, cause written instructions to be provided for administration and use of a mixture of OP-1 and Calstrux which was not included in the FDA-approved labeling for OP-1, which acts resulted in OP-1 being misbranded. Each of Counts 7 through 12 alleges a separate instance of the provision of unapproved mixing instructions to a physician or a hospital.

Those are the allegations that are made by the indictment. Whether they are true or not is up to you to decide on the evidence in the case. The defendants, as I've said, are presumed to be not guilty of these charges unless the government proves otherwise by the evidence and proves it beyond a reasonable doubt.

So with that stage set, we'll ask the parties now to start with the opening statements. The order will be the government will go first and then we'll hear from each of the defendants in turn.

Ms. Winkler for the government?

MS. WINKLER: Thank you, your Honor.

Good morning. May it please the Court and counsel, ladies and gentlemen of the jury, you're going to hear evidence over the course of the next few weeks, and it's a story about failed expectations. The --

THE COURT: Excuse me, Ms. Winkler. It would just help us all to try to get that mic to you.

Sorry to interrupt.

(There is an interruption in the proceedings.)

MS. WINKLER: So the story is about failed hopes and expectations. Stryker Biotech, LLC -- that's a limited liability company -- was a small company that was set up in Hopkinton. And it was set up by Stryker Corporation, which is a big multinational corporation. The reason they set up Stryker Biotech was to bring to market a product called OP-1. And you'll see OP-1 in the course of this trial. This is it. This is OP-1. It's that little bit of powder in that bottom of that jar, all right?

The powder is a protein. It's designed to be used during surgeries to stimulate bone growth; to help bones generate more bone, if you will. And this powder, if they had been able to prove it was effective, had lots of potential applications. It could be used in spine surgeries. It could be used for disk disease. You'll hear evidence in this trial that the market -- the potential market -- and the applications for this product were over a billion dollars. That's what Stryker Biotech was reaching to get.

Now, in the United States we have the Federal Food and Drug Administration, the FDA. And the FDA's job is to look at the evidence with regard to medical devices to see if they are

safe and effective before they are sold for use in the American public. And the FDA requires reliable evidence, they require studies, that actually show that a product works and that it's safe.

You're going to learn that Stryker Biotech failed to get the full premarket approval that they wanted for this product. Their studies were not adequate. The FDA did not give them -- and this was like 12 years ago. They did not give them the PMA that they were first looking to get.

So what did they do instead? They went back to the FDA and they asked for two very limited, narrow exemptions to the requirement to get that full approval, premarket approval, and the FDA granted that. And those very narrow restrictions we will talk about later, I'll tell you a little more about. But the reason they got those, it's to market to a small number of patients. And so they had at least an ability now to go out and talk to doctors. And they did.

And they reached another problem. Doctors took a look at this and they had complaints about it. It handled poorly, like wet sand; it didn't have enough volume for the doctors, for using during surgery; and it was too expensive. This is $5,000 worth of this particular powder.

So what did Stryker Biotech do? They developed another product: Calstrux. This is Calstrux. Calstrux is also in powder form but it's mixed with a saline or other

product. You'll hear different mixing instructions. But when it's mixed, it turns into a ball that's like Play-Doh or some other malleable -- you know, you can move it, you can push it. And so what they did at that point was promote to doctors mixing this powder in with this powder and making a bigger ball of stuff, a bigger ball that the doctor could use.

So now they had something that the sales force could sell. It handled better; it was less expensive, because at that point they told the doctors you could use one of them instead of the two that were required on the label. And then they were able to together mix those two and convince doctors that it was something they should buy.

Now, the evidence that you're going to hear is that all of these defendants knew that promoting the mixture of OP-1 and Calstrux to doctors was illegal. That mixture was not approved by the FDA. That mixture was never tested, studied clinically, by Stryker Biotech, LLC. They did not know if it worked, they did not know if it was safe, and they marketed it anyway to doctors in the United States. It's the patients who were put at risk by that sort of promotion, the patients who don't know they're guinea pigs for this unapproved mixture of OP-1 and Calstrux.

Some of the patients suffered adverse events. Some of those adverse events were serious: There was infection; there was wound drainage. And you'll also hear some stories about

product -- it migrated. It moved away from where it was put in the spine. It moved away from the spine and patients would have problems. And when doctors would go back in, they would find the product in other places where it didn't belong. And sometimes it even grew bone in places where it wasn't supposed to, requiring a second surgery to come in and fix it.

As you'll learn, Stryker Biotech did not know whether that mixture was causing the adverse events or not. They never studied the product. They couldn't tell whether it did or it didn't. But did that stop them? No. They continued to sell this mixture because it made them money. It made them look successful. For the individual defendants, it put money in their pockets. For the corporation, it let them tread water while they were trying to get the full premarket approval -- try to go back to the FDA to get that approval they didn't get.

Let me reintroduce myself. My name is Susan Winkler. I'm an assistant U.S. attorney here in the District of Massachusetts. Trying this case -- or prosecuting this case with me are Jeremy Sternberg and Greg Noonan. They are also assistant U.S. attorneys. It is our privilege to represent the people of the United States.

Let me now tell you a little bit about how we're going to proceed. I'm going to organize this because this may go for about 45 minutes or so. I'm first going to tell you a little bit about the defendants and some of the background, about how

we're going to prove the case; then I'm going to tell you a little bit about more general background: the products, the approvals; and finally, how these devices are sold.

The third section will be a bit of a timeline. So as you hear the evidence at trial, you can sort of put it in place -- witnesses know different things about different times, and it will just help you put it in place. And finally, I'll talk to you just briefly about the indictment that Judge O'Toole just explained to you.

So let me start with the defendants. Who are the defendants in this trial? Stryker Biotech, LLC, the corporation, is one of the defendants in the trial. It's located in Hopkinton. It had a few hundred people there. It had a manufacturing plant up in New Hampshire -- Lebanon, New Hampshire -- and it had a sales force of about 30 people that were spread out around the country. The company is a defendant in this trial because corporations are responsible for what their employees do that's in the scope of their duties and if it's, in part, to benefit the corporation.

One of the people you're going to hear evidence about during this trial is Mark Philip, the president of Stryker Biotech. You'll hear how he set budgets and quotas that ultimately required the sales force to sell the mixture of OP-1 and Calstrux to hit their numbers. You'll hear how he was told to have the stock and the efforts they took were ineffective.

Mr. Heppner, William Heppner, is another defendant in this trial. This man was the national sales director for Stryker Biotech. He was the one in charge of the sales force during the time period of the crimes charged. It was his job to make sure the sales force performed, that they hit those numbers that were in the budgets, that they made their quotas. That was his job.

The evidence will be that he knew the sales force was promoting the mixture of OP-1 and Calstrux; that he knew the promotion of that mixture was illegal; and that he essentially made clear to them that they had to do what had to be done. If they didn't make their numbers, they were put on performance plans; if they didn't make their performance plans, they were fired.

The other two defendants are regional sales managers of Stryker Biotech. The sales force had Mr. Heppner at the top, and then they had four regional sales managers: one in the northeast, one central, one west, and one in the southeast. Two of those individuals are defendants in this trial. One is Mr. David Ard. He was the regional sales manager for the west. Another is Mr. Jeffrey Whitaker. He was the sales manager for the southeast.

Those two individuals each had a number of sales representatives reporting to them. They also knew that promoting the mixture of Calstrux and OP-1 to doctors was

illegal. They knew it was not approved, they knew it hadn't been tested, and they knew their sales force was doing it. In fact, they discussed it with their sales force. And you'll hear evidence of that during trial. You'll hear about how they helped their sales force come up with instructions on how to mix this product, instructions that were never run by anyone, never tested. They weren't approved. They weren't reliable. They were just their best idea on how to do it.

In short, the evidence is going to be that these three men and the corporation knew that doctors had been misled into thinking this product was all OP-1, that they didn't even realize in many cases that Calstrux was involved, and that they would convince doctors to buy it on that basis. And why did they do it? You'll hear evidence that these defendants, the individual defendants, put hundreds of thousands of dollars in their own pockets based on making these numbers, and that the company made additional millions from the sales of -- that were attributable to the mixture.

So how are we going to prove this case? It will basically be through witnesses and documents, like the judge just instructed you. The witnesses will include the sales force. You'll hear from a number of people in the sales force who reported to these individuals and were colleagues of theirs. Some of those sales representatives pled guilty to their own criminal conduct and are cooperating with the

government. You will hear from them.

You'll also hear from doctors and surgeons, some of whom consulted with Stryker Biotech during the time period of the conspiracy, told them at different points that the mixture was ineffective, told them that the mixture came with an excess number of adverse events. You'll also hear from some people from headquarters in Hopkinton, people who were involved in trying to get the sales practices stopped.

And you'll also see a lot of documents in the case. There are a number of documents. You'll see emails between these individuals. You'll see PowerPoint presentations where they were actually trained that it was illegal and they should stop. You'll see some exhibits like these, the Calstrux and the OP-1, and you'll see other presentations that they gave at their sales meetings and communications that they had amongst each other.

Now let me tell you just a little bit about the products themselves. OP-1 is this powder that we were just looking at. And there were two kinds. It was sold two different ways by Stryker. One was OP-1 Implant which was just -- these are the same. This is what it's packaged in, this OP-1 Implant. And this is the powder here. But it's the same powder, it's just one's a brown bottle and one's a white bottle.

The Implant was used for long-bone breaks, things like

arms and legs. Think ski accidents, auto accidents, things where people break their big bones. And it was only as a last resort, if someone had already had surgery and tried to get it fixed and they had to go back in again. The narrow approval they got was for that.

OP-1 Putty was the other application they had, which was the same powder combined with a tiny little bit of powder in another vial. That's how it was approved to be used. And it was for use in the spine and spinal surgeries. And again, it was a last resort. It was after other surgeries had failed and they had to go back in to try again.

Now, Calstrux is nothing but a bone void filler. This powder does not grow bone. This is like spackle that you put in your walls to cover up holes, okay? That's what this is. And there are a number of these bone void fillers on the market, so this was not their flagship product. Their flagship product was OP-1.

Now let me tell you a bit about the approvals that they got. The FDA, as I mentioned earlier, is an agency that's responsible for protecting the American public. They are supposed to assess medical devices before they are sold to doctors or hospitals for use in patients and to make sure they're safe and effective. That's the FDA's job.

And for medical device companies like Stryker Biotech, there are various ways to get those approvals. One of them,

and the one they wanted, was the premarket approval. That's the big approval. That's the approval that for whatever use they get it approved for, it's the one the companies want. It's what Stryker wanted back about 12 years ago and they didn't get, and they tried again later, and during the course of this conspiracy and they didn't get. But that's the way that companies want to get their devices approved.

There's a second way, which is a clearance. And a clearance is what Calstrux got. And for those, if you can show that your device is substantially similar to other devices on the market, you get that clearance. And that's what Calstrux got because there were other bone void fillers on the market, and so it just was clear to be used. It doesn't require the same studies and testing because somebody else has already done those studies and testing. But that's not for OP-1, because OP-1 was a device that had to have studies. It had to be -- because it was going to be used during surgeries, inside us, they had to know that it was safe and effective.

So what did they get instead? They got what's called a humanitarian device exemption to the premarket approval. A humanitarian device exemption is essentially for orphan conditions, conditions that affect very few people in the United States. So less than 4,000. And in their application, Stryker Biotech had to explain how the condition impacted less than 4,000 people in the United States. That's a requirement

for this narrow exemption. That's all they were supposed to be treating, is up to that number.

So they got two of those exemptions: one for OP-1 Implant and one for OP-1 Putty. Those approvals come with some very important restrictions. The first one is they can't make a profit. They can't make a profit because there is a -- I'm sorry. I got distracted by that phone -- there is a -- Congress imposed this restriction to protect patients. It's incentive to get medical device manufacturers to do products for people who really need them. And so they can recover the cost of their research and they can recover the cost of fabricating the device, but they can't make a profit. So that's why they really wanted the big, full market approval, the premarket approval, because they couldn't.

And the second restriction on this very narrow humanitarian device exemption they got was they had to show that it impacted only 4,000 patients. That was not the big market they were hoping to get that was in excess of a billion dollars; it was only 4,000 patients. So they couldn't make more than, you know, 40 or 50 million dollars, depending on how many units were used, for patients in the United States. And you'll hear some evidence about that during the course of this trial.

If you got the full premarket approval, you did not need to show that there was such a limited number of patients,

and you didn't have to report back to the FDA about how many units you sold or that there were still only 4,000 patients. With this exemption, you did.

And the third restriction which you'll hear about in this case is you could not sell these products to a hospital unless that hospital had something called an independent review board. Now, what's that? It's an independent body at the hospital made up of medical people, science people, non-science people. And their job is to protect patients. They are supposed to watch over the use of experimental devices at a hospital. And humanitarian device exemptions are exempt from showing effectiveness -- that's how they get approved. They haven't had to prove it -- so one of the requirements in the statute, in the restriction, is that the hospital -- their independent review board -- has to approve the use of this device before a doctor can use it at the hospital -- they're supposed to.

And those approvals are different for different hospitals. They might approve it for one doctor, they might approve it for a bunch, they might approve it for just what's on the label, they might approve it broader, but the doctor has to use it in accord -- or is supposed to use it in accord with what the approval is in the hospital, and the manufacturer cannot sell to that hospital until that approval is in place.

Now, if you get the full premarket approval, you don't

need to go to the institutional -- the institutional review board first. The institutional review board does not have a say about -- you don't have to get that approval before you can sell. Okay. Enough about those restrictions. But that's why it was so restricted and why they really wanted to get the full -- big full-market approval.

So now let me tell you about how medical devices -- the evidence you're going to hear about how medical devices are sold to hospitals and doctors. You're going to hear from a number of salespeople in this company. And we suspect they're going to tell you about a number of things. They're going to tell you there was a lot of pressure on the sales force. They were expected to make sales. They had quotas. If they didn't meet those quotas they were put on performance plans. If they didn't succeed on their performance plans, they were fired. So making the numbers matter to the sales force, in addition to the fact, if you exceeded and did better, you could put, you know, extra commission in your pocket.

You're going to hear about how closely monitored they were. They got daily score cards that showed how many units they had sold of Implant, of putty, of Calstrux; how many IRB approvals they had. They kept very close track of the sales force and how they were doing.

You're going to hear evidence that these defendants

were involved in training the people who were under them. They rode along with them to make sales calls sometimes; they evaluated them; they met with them; they had national sales meetings where all 30 or so of them would come together and talk about what they were doing.

And you're going to hear evidence that they could rarely sell Calstrux, this bone void filler, by itself. There were other bone void fillers on the market. This was nothing special. And you're going to hear that they just didn't sell a lot of this without OP-1, all right? That's important. These defendants knew that. They knew it was hard to sell Calstrux without OP-1.

So how did they sell it? I'll come back to why that's important in a minute. Let me just tell you how they sold it. The first thing a sales representative had to do was figure out which doctors might use this product. And there were two kinds of doctors, trauma surgeons and spine surgeons, that they had to find. But they had to find surgeons who worked at hospitals who had institutional review boards because, remember, they had to have that approval.

Next, they had to go in to see the surgeon. And those surgeons are pretty busy. And they had to get time with the surgeon. And then they had to convince the surgeon to use this product rather than some other. And that is where you're going to hear in the evidence that some of the false and misleading

statements to doctors were made, is in those meetings, those one-on-ones between the sales representative and the doctor.

And what were some of the false statements that were made? Among others, you're going to hear that the sales force would hand -- a salesperson would hand a ball of Calstrux that they had mixed up so it was like the Play-Doh ball. They would hand it to the doctor and they would say, "This is what OP-1 is going to feel like in surgery." And the doctor would sit there and play with the ball.

They wouldn't tell the doctor that it was a separate product, that it was Calstrux as opposed to OP-1. And the doctor assumed wrongly that it was OP-1, the product that had some approval, as opposed to a mixture of OP-1 and Calstrux which had no approval at all, which had no testing at all, and which they didn't know was safe or effective.

Another dishonest thing that would happen in those meetings is that a salesperson would tell doctors, "This Calstrux, this is our carrier, or extender, for OP-1." Remember I told you doctors were complaining that that handled like wet sand and it didn't have any volume and it was too expensive? So they would say -- because they were supposed to use two of these if they were doing spine surgery. Two. That's over $10,000 by the time they pay for it.

So the sales reps would say, "Use this. Mix this Calstrux together with OP-1. You'll get much more volume, it

will be less in price because you'll only have to use one, and it's going to handle better because it's going to be like Play-Doh instead of like wet sand."

Well, the doctors thought when they said "this was Stryker's carrier," Stryker, a big multinational corporation, that they had some -- and it was Stryker Biotech's, but they knew they were connected. They thought there was something behind this. They thought there was some study behind it. They thought there was some basis for the sales force to say this was a carrier for OP-1. There was none. It had never been studied. They had no idea. That's another way they misled doctors.

A third way they misled doctors: When they complained it was too expensive and they said use one, you don't have to use two, and when the FDA approved it, even with the exemption for showing it was effective, they said you had to use two. They were supposed to promote it in accord with the label, and they were telling doctors it was okay to use one. Again, doctors assumed there was something behind that. They must have some testing or they must have some approvals for that. They had none. There were other misrepresentations that you'll hear about during the course of this trial but those are some of them.

Now, if the doctor decided after this meeting with the sales rep he wanted to try it, he had to go get IRB approval.

And you'll hear that's something the doctor has to do, but the Stryker sales reps helped out. They did the paperwork; they ran it back and forth, did whatever it took. If they got approval at the hospital, then the sales force had to get the product stocked at the hospital. So they would take -- and frequently they would do it on what's called consignment. They would take these boxes, and they would put some in the hospital supply area in the refrigerator, wherever it had to go. And it would sit there until it was used. Most of this OP-1 was sold that way, on consignment. It sat in the hospital and it was held for sale at the hospital until the doctor needed it. And then during surgery the surgical staff would go get it, bring it to the surgery, and they would do what they had to do.

Back surgeries are very long surgeries. The Stryker sales representatives were expected to be there. And why? So they could help the doctor as needed. And one of the things they were expected to do, you're going to hear, is to provide the doctors instructions on how to mix Calstrux and OP-1, the mixture that had no approval and had never been tested.

And in some cases they had great big territories -- there were only 30 of them for the whole country -- they couldn't be there. So they would send written instructions to the doctor or to the doctor's staff to tell them how to mix it because they couldn't be there to point it out and say, Take this and take that and put them in the cup and stir them up

together. They weren't there to do that. So sometimes they wrote them down. Sometimes they left them pasted on refrigerators in the OR.

After the surgery you'll hear that the -- oh, this was another place -- it was during surgery where misrepresentations were made leading up to -- when they gave them instructions, those instructions implied that they had some basis for it. You know, they were on Stryker letterhead. They looked like instructions; they were all printed up. But they didn't have any approvals. They had never tested it. They didn't know what worked.

And worse, they had 30 different sales reps, as they told management, doing 30 different things because nobody knew what worked. So the sales reps were putting together these recipes. These weren't recipes that came from any study or test; the sales representatives were doing it, telling doctors how to mix two products to be used on patients with absolutely no basis for it.

So after the surgery was done, the -- you'll see at some point they had -- inside each of these boxes they have labels. And these labels come with stickies. And there would be a delivered goods receipt. And they would peel these off and they would put them on there so they knew exactly what had been used: which box of OP-1, which Calstrux. And the reason they did that is so they could send the product -- I mean, send

the receipt back to Stryker and then Stryker could do the bill. That's when the billing happened.

Now I'm to the third part. This is the chronology. Let me tell you a little bit about how things developed in this company. The Calstrux was available to them and they got a clearance from the FDA in about 2004, and they launched it in about 2005. And adverse events started to happen in 2005. They started to have problems with the mixture of OP-1 and Calstrux. And so in September of 2005 they sent a letter to physicians, and they told physicians that they had had some adverse events with the mixture -- with mixtures with Calstrux. But, note, they didn't mention OP-1, their flagship product. And the evidence you will hear at trial will show you why.

They then, during the fall of '05, started to do a study on the mixture of OP-1 and Calstrux. You'll hear that it never got off the ground. It never got FDA approval -- which you have to have to do a study of a new investigational device -- and the doctor pulled out. So they never did the study. So the adverse events were continuing.

And by January 2006 you're going to hear that the vice president of regulatory at Hopkinton started to get concerned. The adverse events were continuing. So she went to the national sales meeting, and at the national sales meeting where all these defendants and other people that you're going to hear from were present, she learned for the first time that

representatives were promoting the mixture of OP-1 and Calstrux in physician offices; that representatives were present in the OR, the operating room, and directing the doctors how to mix the two; and that they were promoting all kinds of different recipes, none, of course, which had been approved or tested -- some would say mix with blood or saline, some would say use different amounts of liquid, some would say roll it in different ways: some would say cigars, some would say Tootsie Rolls and some would say bricks -- and she got very concerned.

She met, you will hear, with Mr. Philip, the president, and Defendant Heppner, and she told them it was illegal, that it had to stop, that they needed to tell doctors about the adverse events, and that they needed to make sure that the sales force was trained to stop doing the illegal promotion of that mixture.

Well, what happened then? There was a large objection to going forward in that way by the sales force. And at trial you'll hear the words of these own defendants because you'll get to see the emails between them. And when the sales force learned that this letter was going to go out -- and the letter that they drafted actually said there are adverse events associated with the mixture of OP-1 and Calstrux.

And so, for example, Mr. Whitaker writes to Mr. Ard and to Mr. Heppner and others expressing his concerns about it. And some of the things he said are a lot of potential surgeon

questions. He said, "Potential surgeon questions: Well, what are the adverse events?" And he goes on to say, "Is this all the product I get?" seeing the volume of just OP-1 Putty. And "Why should I use OP-1 now that you don't have a big advantage in handling?" And then he wrote some -- he said -- he goes on to say with his -- the surgeon questions that he expected, "This stuff doesn't hold together very well and has very little volume. What else can I mix it with, if OP-1 Putty? This stuff is it like wet sand. What can I mix it with if implanted?" "Do I need to look back at all of the patients I've done? I've used a lot of this TCP" -- "TCP" was the name for Calstrux when it first came out -- "and not had any problems," with most surgeons. "Should I stop using it?" He was concerned if that letter went out surgeons would stop using it.

Then he had representative questions that he thought they would get if they told the representatives about this adverse -- this letter to doctors warning them about adverse events. "How many surgeon complaints, adverse events, have been reported?" "Do you know what this is going to do to our OP-1 sales?" "Do you know what this is going to do to our Calstrux sales?" "All my big users mix OP-1 with Calstrux and that's why they use OP-1." "How do I keep their business?" "If I'm in a case tomorrow with a new or current user, do I need to tell the surgeon not to mix OP-1 and Calstrux?" "Are

we sending out this letter just based on anecdotal complaints from reps where we may not know if TCP was the reason?" "How am I supposed to sell Calstrux after the second letter goes out?" "Have we determined whether there's another ideal carrier for OP-1 that is out there?" "How can we even sell Calstrux at all if we're sending out letters saying it has problems and needs to be researched further?" "Are you going to reduce or eliminate my quota?"

And he concludes his email to the other defendants and others saying, "Many surgeons are just handed the product prior to implantation and they think it's all OP-1." They knew, the evidence will be, that the surgeons had been misled and thought it was all OP-1.

In response, they were going to send this letter both to surgeons and to the hospital institutional review boards. And Defendant Heppner wrote an email. He was very worried about the institutional review boards. He noted in his email to -- and this email went to the other defendants, David Ard and Mr. Whitaker, and it also went to the president, Mark Philip. And he said that "all of these missions are to protect patients. A letter like this will be cause for swift action."

And what were some of the things he said he was worried about? He says, "I strongly advise that we do not send this letter to IRBs." And his concern: "They will cease all OP-1 usage in the hospital immediately until this action is

clarified with Stryker and the FDA." He was concerned that PIs -- those are principal investigators, the doctors who supported that approval at the IRB -- will be notified to provide a list of all patients treated with OP-1 with charts, adverse events, outcomes, et cetera. "This opens Pandora's box on other users that" -- this PI doctor -- "may not have known about, him potentially getting in trouble with the hospital as he has used OP-1 in primary fusions in a large number of cases and other off-label usages of OP-1, et cetera." The day after he sent that email, you will hear that the decision was made not to send the letter to warn institutional review boards at hospitals about those adverse events.

Now, one of the things I told you was that the regulatory vice president wanted training, and they did that training on March 1st. And you will see evidence at trial where they were told: "Do not promote off-label. Do not mix Calstrux and OP-1 Implant. Do not share recipes. Do not recommend the use of Calstrux and OP-1 Implant. Do not give directions for mixing Calstrux and OP-1 Implant. No off-label promotion or off-label activities will be tolerated." They were also told that it was illegal, that it was criminal, and that it was a serious offense if they did those things. That training was given to them on March 1st in a big conference, a nationwide teleconference, in which these three men participated.

Now, as part of that conference they also talked about the letter. And the sales force had a lot to say about it. And you'll hear about some of those things. They were very concerned that sending out that letter would cease all sales. They would lose. They would stop. "If they send out this letter," the quote is, "they will kill all OP-1." That was what we believe the evidence will be when you hear it. And after that teleconference and some more discussion, they decided not to send the letter at all.

So what happened at Stryker Biotech with the sales force after this training was given? The evidence will be that nothing changed. Why not? Stryker Biotech did not change the budgets. They did not change the quotas. The sales reps still had to sell OP-1 and Calstrux to keep their job. They got bonuses if they sold more. They didn't make the changes to let the sales force stop selling the mixture of OP-1 and Calstrux.

One of the things you will hear is that some evidence -- obviously, Defendant Heppner told the sales force to go back and get the written mixing instructions they had left in hospitals. Pick them up and bring them back. Don't leave them lying around. And you'll hear some of the sales force understood that to mean: "Don't leave evidence where we can get caught." But they fully understood they had to continue to explain to doctors how to do this mixing, and that that was something they would have to do to sell the product.

That's why ultimately the training was ineffective, because nothing else changed for these salespeople.

And even those salespeople who tried to stop mixing, who tried to stop selling the Calstrux, they got in trouble. You'll see evidence at this trial that Heppner -- Defendant Heppner sent an email in May of 2006, right after this training, telling those that were -- "If you're getting this email, unfortunately, your Calstrux numbers fell below ten units last month." In other words, if you don't make your sales, you've got problems at this company. And Mr. Heppner goes on to say, "The issues we had in the past have been put to bed and substantial dollars are there to be made." He was pushing the sales force to do -- we believe the evidence will come out to you in trial that he is pushing them to make their sales.

So the sales continued. The sales of the mixture of OP-1 and Calstrux. They continued to promote it to doctors. They continued to give discounted proposals to hospitals where they could buy the two together cheaper if they got them. So they did try to deal with the adverse events at least in some ways. And why? Because by -- in part, because in the middle of the summer the FDA saw some instances of these adverse events and -- between the mixture of OP-1 and Calstrux, and they decided to send out a letter to re-label Calstrux. And in that letter they told doctors that they should not be mixed.

What they said, though, was Calstrux should not be used in combination with other products, that adverse events include localized induration, swelling, inflammation, wound drainage, infection and device migration. That's where it moves out of the place where it was set.

And they also noted that "Stryker has identified an increased trend in adverse events associated with the combination use of Calstrux." Seven of the events required surgical intervention. You'll see this evidence during trial. But they were concerned about it and they sent the letter. You'll notice what the letter never mentioned: OP-1. And the evidence at trial will tell you why.

They also, during the course of this time frame, asked doctors to go back -- some of their doctors that they worked with a lot -- and to analyze their own experiences. And one of their doctors told them in February 2006 that the adverse event rate was higher than the norm, and by later that year, he told them the mixture of Calstrux and OP-1 was ineffective. Nothing changed.

They went to another doctor who they went to to try to figure out a technique that might work better to stop the migration and some of the adverse events. And he used a brick. And so they were telling the salespeople about this brick and that maybe that was a better way to do it: make it dryer, make it so it doesn't move out of the surgical site as much.

That doctor ultimately told them about a year later, in early '07, that the -- that it should be used -- the product should be used according to the label: two vials -- two units -- of OP-1 as originally supposed to be constituted, what's in this box; that they should not use it with Calstrux. That that wasn't the best way to do it.

But nothing changed. The quotas were made the same. The budgets continued to go up. They were expected to hit those sales. They didn't have an option. The sales force was out promoting this mixture of OP-1 and Calstrux even though they knew it was illegal. They had no basis for the instructions. They had no basis to promote the mixture. It had never been tested. It had never been approved.

Let me now briefly turn to the indictment. The judge told you about the indictment, what's actually charged in the 12 different counts. A couple of things I want to note for you by way of evidence in that connection. The first charge is a conspiracy -- that all of the defendants are charged in a conspiracy. And we believe the evidence will show beyond a reasonable doubt that they did conspire to defraud the FDA by using deceit and dishonest means to frustrate the FDA's lawful function of ensuring the health and safety of the public by making sure that medical devices that are marketed and distributed in the United States were safe and effective for their intended uses.

And we've talked about some of those dishonest ways they did that, one of them being that they handed the ball to the doctor. And the doctor assumed it was OP-1, which is misleading because he doesn't know it's a mixture. And they handed other physicians -- and to some physicians they just affirmatively misrepresented this is what OP-1 will be and did not tell them. So that was affirmatively misrepresenting what it was.

They knew about the adverse experiences with OP-1 and Calstrux. They didn't tell the doctors. They knew about the adverse events, that it was material information to IRBs. Defendant Heppner says he's worried they're going to cease all usage immediately if they don't -- if they get information about that -- those adverse events.

They misrepresented to physicians that Calstrux was a carrier for OP-1, that it was somehow developed for that purpose, when it had never been tested that way. And they suggested mixing instructions as if there were some sort of approved way to do it when all it was was a bunch of different ways by a bunch of different salespeople on how they thought maybe it could be mixed up. And that's what was used in patients.

Now, we also have to show at least one overt act happened in the Commonwealth of Massachusetts. We think you'll see several of those during the course of this trial, including

some that we've talked about today, setting those quotas that required them to make the sales and the decisions not to send out the "dear-doctor" letter.

The wire fraud count, as your Honor explained, was about the emails. And some of those emails that are the subject of those counts I've talked to you about already. Mr. Whitaker's email where he worries about that the doctors have been -- they all think it's OP-1 and where he worries about what surgeons are going to say, and stop using it, and the sales reps about the fact that quotas aren't changing, that's Count 2.

Count 3 is Mr. Heppner's email which deals with the IRBs and the fact that they'll stop usage if they get the information. Count 4 is Mr. Heppner's email to the laggers who aren't making enough Calstrux sales. Count 5 involves Mr. Ard where, in October of 2006 -- and you'll see this during trial -- he sends one of his sales representatives not only some paperwork, invoices and the like, he sends them mixing instructions after they've all been trained that this is illegal. And Count 6 involves an email from President Philip -- Mark Philip, the president of Stryker Biotech -- who was sending out increased quotas for the sales force, which they could not meet, the evidence will be, without selling this mixture. Those are Counts 2 through 6. There was a scheme to use those false and deceptive things we were talking about

earlier to defraud hospitals and doctors, and they used the wires to do it.

And finally, the misbranding counts which are only against the corporation, those are Counts 7 through 12. And we believe the evidence will show beyond a reasonable doubt that those products were held for sale on consignment at the hospitals, and while they were there employees of Stryker Biotech sent out mixing instructions, all different kinds, and that that was an act -- those instructions were not part of the label, they did not have adequate directions for use, they were sent to doctors, and they misbranded -- that's the legal term -- the medical device that was being sold by the corporation, and it was done with an intent to defraud and mislead both the FDA -- because the FDA knew nothing about these mixing instructions or that they were out there promoting this mixture, that's what this evidence will be -- and doctors -- by misleading doctors about the nature of the approvals and the nature of the device.

All of these crimes were done to evade the FDA's regulatory authority, to approve devices before they're sold for the use in the American public. And it was done to put money in their own pockets, it was done to make the subsidiary look good to the corporation, to keep them treading water while they tried to get that full premarket approval that they were never able to get because they never had the studies to show

that OP-1 worked.

In summary, Mr. Sternberg will talk to you at the end of this case. He's going to ask you to use your common sense to understand the evidence, to find that the government has proved beyond a reasonable doubt that these defendants committed the crimes with which they are charged, and he's going to ask you to return a verdict of guilty.

Thank you.

MR. O'CONNOR: If it please the Court, good morning, ladies and gentlemen. My name is Brien O'Connor. And I also want to introduce my partner, Josh Levy -- and Cori Lable and Aaron Katz -- if you would stand, please -- who are going to be assisting us throughout the trial.

It is my privilege to stand before you and to represent Stryker Biotech in this case. On behalf of all of the defendants, first, I want to thank you for your jury service. We all know that serving as a juror is not only a big time commitment, but also requires hard work and consistent attention to the evidence, especially in as long a case as this promises to be. We all recognize that jury service, especially in a complex criminal case, is an incredibly important civic duty and contribution.

This, ladies and gentlemen, is a criminal case. Over my more than 25 years as a lawyer, more than a decade in each of the public and private sectors, I've learned that criminal

cases are different and more important than regulatory actions, commercial litigation, and every other type of case. Criminal cases involve the most serious kind of government action and core individual rights and liberties. There's just more at stake, ladies and gentlemen, in a criminal case, so the process is really important.

So what kind of case have the prosecutors brought? Ms. Winkler speaks softly, but let me tell you: This is a federal felony criminal case. Not a civil enforcement action, not a regulatory action and not even a misdemeanor criminal case. In the spectrum of legal proceedings, a federal felony criminal case is up here, and everything else is somewhere down here.

The prosecutors have told you that our clients, Stryker Biotech, Bill Heppner, Dave Ard and Jeff Whitaker, engaged in criminal fraud. They say that Biotech, Heppner, Ard and Whitaker manipulated, lied to, cheated and deceived brilliant and experienced neurosurgeons and spinal surgeons into using Biotech's OP-1 and Calstrux together. They also say that the defendants engaged in a criminal conspiracy to defraud the FDA, mainly by tricking those surgeons. Finally, they say that the defendants intentionally violated the criminal law for money, for money they had no right to receive.

The evidence in this case, ladies and gentlemen, from the witnesses and the documents, will prove no such thing.

Instead, it will show that the government's claims are wrong. What the evidence will show is that this case is a terribly misguided prosecution and a gross injustice to Stryker Biotech and these men. Surgeons were not tricked into using the OP-1/Calstrux combination; they chose to use it because it worked.

On the subject of money, let me just say at this point that the claim that these defendants, these men, would engage in intentional criminal conduct against surgeons they valued and respected highly, and against the government agency that was critical to their future, the FDA, all to make short-term money makes no sense and did not happen.

Now, I want to say just a few words about each of the individual defendants. Bill Heppner came to Stryker Biotech in 2002 with eight years of experience selling medical devices. While at Biotech, Bill earned the respect of his surgeon clients and his peers alike. He became known as a positive motivator, a leader, and a champion of the sales team.

Dave Ard joined Biotech in August of 2005 as the western regional sales director. Dave joined Biotech because he, like many others, was very excited about the healing powers of OP-1. Dave had a strong reputation already in the industry and with surgeons in his territory for being a straight-shooter.

Jeff Whitaker, like his two codefendants, is a family

man. He has a beautiful family. He came to Biotech with more than 15 years of experience in the medical field. Jeff was a hard-working sales rep first who fostered long-term relationships with surgeons. Biotech named Jeff its southeast regional sales director in 2005.

Let me say this about Bill, Dave and Jeff: Never in a million years did any of them consider even remotely possible that anyone would point the finger at them and tell them they were criminals, accuse them of lying to or cheating the very surgeons they were trying most to help.

Before I go any further, I do need to say something about adverse events. Ms. Winkler's presentation is misleading. The evidence in this case will show that the rate of adverse events in surgeries involving the OP-1/Calstrux combination was only one half of 1 percent. That is 63 adverse events out of over 10,000 surgeries. Also, the term "adverse event," it's a specialized medical term that refers to anything that goes wrong in a surgery no matter how minor and not because the surgeon thinks the device has anything at all to do with the event, all right?

So on that point, the adverse events that surgeons reported to Biotech were the kinds of events common to all trauma and spine surgeries. Many of the events were minor, things like fever or swelling, issues that resolved quickly and don't cause permanent harm. When you see photos of these

surgeries -- and there won't be many, thankfully -- you'll understand why these surgeries result in some adverse events: 63 out of 10,000. Also, importantly, the prosecutors have conceded in this case that they can't prove that the combination of the OP-1 products with Calstrux caused any of the adverse events.

Now, you may be wondering how this case got started. Why are we here for so long, right? Was it triggered by these adverse events or patient deaths? No, not at all. You heard from Ms. Winkler that hospital IRB committees had to approve the use -- and IRBs are institutional review boards, not independent review boards, institutional -- had to approve the use of OP-1 in hospitals because of the nature of the HDE approval.

Well, in 2007, right in the middle of the conspiracy, as the Court said -- during the supposed conspiracy against surgeons and the FDA -- Biotech discovered that one of its sales representatives, a man named Don Allard who's now deceased, had violated company policy by forging an IRB approval form. The company immediately terminated Mr. Allard, and its legal and compliance people began an intensive investigation, including these managers, by the way, to determine whether there was a broader problem. Ultimately, the company identified a few of Allard's colleagues who also had violated company policy by forging at least one IRB approval.

The company promptly terminated those employees too.

Beginning in September of 2007, the company also made four voluntary written reports about the IRB misconduct to the FDA, to the regulator. So the point is the case didn't begin with surgeon or patient complaints or adverse events. But also, think about this for a minute. Think about Biotech's disclosure of the IRB misconduct in the middle of the supposed conspiracy to target and defeat the FDA. The notion that at the same time the company was reporting violations of its policies to the FDA it was also participating in a criminal conspiracy against the FDA makes no sense at all.

Now, what do the prosecutors say the defendants did to warrant being here, being charged with serious criminal felonies? The indictment -- I think you've got a sense of it -- recites a grab bag of unclear scattered complaints about the company's marketing practices. The prosecutors throw up against the wall vague and inconsistent allegations hoping something will stick. The bottom line on these allegations is that they don't stick. Not one of them proves intentional wrongdoing of any kind and definitely not criminal fraud.

Before going through some of the specific complaints, I do want to talk with you about the patient conditions, how surgeons historically have tried to fix those conditions and the formation of my client, Stryker Biotech.

This case involves two extremely difficult procedures

that trauma and spine surgeons perform. First, they surgically repair long-bone non-union fractures, really bad breaks, in the tibia and fibula and the femur and the humerus, breaks that haven't healed after first-line treatments and other surgeries have failed.

You may also have heard about slipped disks and ruptured disks in the lower back which can cause intense nerve pain in the back and the legs. When surgeons remove the bulging parts or the ruptured parts of those disks, they need to fuse the vertebrae around them.

We have brought a little model. And for those of you who can see, the dark area here, those are the disks. And when they rupture -- here's the lumbar, here's the cervical up here, here's the back of the skull, here are the hips, which I'll mention in a moment -- but what happens is, the surgeons go in and they put in the OP-1 and the Calstrux together to hold together, you know, two or more vertebrae, to fuse it, to stabilize the spine. So that's how it works.

Now, I am going to ask you to pull out your monitors, please, for a moment -- I'm sorry for those in the back. I should have said it at the outset -- because I do want you all to see -- all right. Over the past two years in this case I've had the privilege of learning about growing bone. I know that -- I know now that growing bone requires three basic elements: First, you've got to have live cells. And live

cells you get by scraping the bone, or debriding the bone, so that they're exposed and so they can help the growth. Second, you need stimulation, stimulation of the bone-growing cells. Third, you need some kind of structure, or matrix, for the bone to grow on. So when we're trying to fuse a spine -- or surgeons are -- they're trying to grow bone across a structure.

Before OP-1 -- and its only competitor, InFuse made by Medtronic -- you may have heard of Medtronic. They had another stimulator, agent. Before they were approved the only way surgeons could stimulate bone-growing cells was to use iliac crest bone. That's in the hip bone. That requires an extra surgery on the hip and the removal of bone and bone marrow so that it could then be transported, or moved, into the surgical site in the back or wherever the long-bone fracture is.

So the problem was there were real problems with iliac crest grafts. What are they? Well, hip surgery is very painful. Also, there's a limited amount of bone to use, so if you need more stimulator than the hip affords, you need it from somewhere else. Third, a lot of patients just aren't eligible because they're smokers or diabetics or have vascular disease, they're osteoporotics, elderly. They can't use an iliac crest graft. But also, two incisions, more time in the operating room, more chance for infection when you've got two surgical sites instead of one. So those problems led scientists to research whether bone morphogenetic proteins could be used to

create an alternative stimulator graft material.

So let's briefly talk about the discovery of one of those stimulators in the formation of the company. Bone morphogenetic proteins exist naturally in the body. They were first discovered and named BMPs, or bone morphogenetic proteins, in the 1960s by Dr. Marshall Urist, a brilliant scientist at UCLA who trained right here at Mass. General. In fact, Dr. Urist was later nominated for a Noble Prize in medicine for his research on bone physiology and bone morphogenetic proteins.

Urist's discovery of BMPs led to 30 years of scientific research to identify BMPs that could have therapeutic benefits to patients. In the 1980s a group of Tufts scientists over in Medford began developing the BMP7 molecule. In 1985 those scientists formed a Hopkinton, Massachusetts-based start-up small company to develop BMP7. That start-up merged into Michigan-based Stryker Corporation, my client Biotech's parent company.

Stryker Corporation was founded in 1941 in Kalamazoo, Michigan, by a Midwestern surgeon named Dr. Homer Stryker. For the past 70 years, building on Dr. Stryker's hard work, creative genius, Stryker Corp. has been an inventor of a lot of medical devices: joint replacements, hips and knees; surgical tools; diagnostic machines used to detect cancer and other serious health conditions; spinal implants. You may have seen

their hospital beds and stretchers. Stryker Corporation employs over 11,000 people in this country and over 20,000 people around the world. Big company? It's big. It's not giant; it's big. And it's good.

Now, at this point, it's high time, I want to introduce Stryker Biotech's corporate representative, Beth Staub. I'll ask Beth to stand. Beth has been at Stryker Corporation for over 20 years. Since 2005, she's been the vice president of regulatory affairs and quality assurance. Beth chairs a steering committee of the regulatory leaders of all the Stryker businesses which oversee Stryker's compliance with FDA rules.

In 1991 Stryker Corporation formed Stryker Biotech. Why? Well, to continue the research of those Tufts scientists. Stryker Biotech spent the next 20 years developing BMP7 for bone growth, and also for cartilage, disk, kidney and heart tissue regeneration.

So what is OP-1? First of all, it's a funny name. Its real tradename is osteogenic protein, but you're going to hear all of the witnesses talk about "OP-1" which is why we do it. OP-1 is derived from BMP7. OP-1 actively recruits live bone cells and helps patients' own bodies grow bone. OP-1 Implant and OP-1 Putty were never sold directly to the public but were marketed only to surgeons and were sold only for use in the operating room. So first: Implant. That was the first

of the two approved, and it was approved in 2001. And it was approved for use in these long-bone non-unions: for use in trauma patients, terrible long-bone breaks, hadn't worked, hadn't been cured by other surgeries, the patients had run out of options.

Putty: approved in 2004 for use in the spinal fusion, for patients who had previous low-back spinal surgeries that failed. Now, what kind of patients? What kind of patients? Really sick ones on the OP-1 Putty, all right? Patients with really weak bones. And you're going to see it when some of the experts testify: smokers, diabetics, people with vascular disease, with lots of prior surgeries.

Let me talk briefly too about the FDA approval status of the OP-1 devices. First of all, Ms. Winkler says in '01 the FDA said no to OP-1 approval. Well, that's true with respect to Implant. They said not enough patients, not enough data. So they suggested what is coming, which is the humanitarian device exempt request and then approval, okay? So both of these products were approved under a so-called HDE, or humanitarian device exemption.

HDE approval is designed by the government to encourage good design -- discovery of devices to treat patients with rare and serious conditions. HDE products had been designed to treat 4,000 or fewer patients annually. There's no limit or cap, but they have to be designed for that.

Hospital IRBs, the institutional review boards, have to approve the use of HDE products in the hospitals. They also have to approve PMA-approved products, by the way. Manufacturers of HDE products are not allowed to make any profit -- no profit -- on sales of HDE products.

Before the FDA can approve a humanitarian device, it must find two things. This goes to safety and effectiveness, right? That there's no unreasonable or significant risk of illness or injury, in other words, it's safe; second, that the probable benefit of the product to health outweighs the risk of illness or injury. So it's a real approved product and for a good reason. Those two reasons.

But the most important point now in this case is that throughout the relevant period both OP-1 products had legal FDA approvals and the two products were legally available for surgeons to use. So how did surgeons use OP-1? Let me just hold up -- and I will. This is not an empty bottle; it's a full bottle -- it's a full bottle of OP-1. And on your screens you see a graphic of it that the company has used.

Now, OP-1 was an amazingly powerful stimulator, much more than bone marrow that you can get in the iliac crest surgery. But you will hear that in some situations when there are large voids in a spinal column -- you can see how large these voids can be -- surgeons saw a need -- wanted filler, you know, other material for more volume. Remember, BMPs, like

OP-1, provide only stimulation but not the structure for the bone to grow on. Think of the structure as scaffolding like at a construction site or other types of scaffolding for the new bone growth. Different surgeons had different preferences as to which scaffold material, or structure material, they'd use in what proportions when used with OP-1.

So what's Calstrux? Please take a look at your monitor. It is a BVF, or bone void filler, with tricalcium phosphate that exists naturally in our bodies and is in the outer layers of our bones. Tricalcium phosphate is an ingredient in milk, in cheese, in toothpaste, even in Gerber baby food. So we've got some bananas, we've got some apples, we've got tricalcium phosphate right here. In other words, it's a generally safe substance.

Calstrux was created by Biotech in 2004 and got a so-called 510(k) approval from the FDA. What does that mean? That means when there are other products already on the market that your product is substantially equivalent to, the government will say, "We don't need the clinical trials." You can have it approved just as long as you're going to use it in the same way that those previously approved products that your product is substantially equivalent to, you know, that those labels are followed.

Surgeons chose to use Calstrux like they used other bone void fillers for years before for that scaffold to grow

bone across and for volume to fill voids during spine fusions. Unlike OP-1 which stimulates the bone cells, Calstrux is an inactive product. Sometimes Calstrux would be used alone as a bone void filler, like where there's a trauma and a divot in a bone, or a surgery that creates a divot in a bone, it would be used -- and usually and oftentimes with patients who heal fast, children and the like.

But more often, surgeons chose to combine Calstrux with other graft materials in bone grafts including OP-1. Now, importantly, experts will be in here to testify that mixing a product like Calstrux with OP-1 Implant or putty doesn't change how OP-1 works. It doesn't change it. It doesn't create a new, what they call, mechanism of action, and it does not cause a chemical change in OP-1.

The evidence will show that OP-1 produced phenomenal results for patients, many of whom were on the verge of losing limbs or afraid they'd never live again without pain. You're going to hear about Bryon Friedman of the U.S. National Ski Team who shattered his lower leg in 2001 at the World Cup in France. We will show you his high-speed downhill crash on tape. Bryon suffered horrible compound fractures of his tibia and fibula. The picture that you have here is after the surgeries where they tried to fix it.

Bryon was afraid that he'd never walk again without pain until he was treated with OP-1. You're going to see how

that leg changes with another graphic we'll show you later. Bryon ultimately returned to the U.S. National Ski Team and skied again in the World Cup.

You're going to hear about a local probation officer named Rachel Joyce, who shattered her tibia in multiple places. Rachel endured numerous failed surgeries over 22 months, lost work, and was faced with the prospect of amputation. You will hear that OP-1 saved Rachel's leg, changed her life, and allowed her to realize her dream of dancing at her daughter's wedding.

These success stories go all the way back to 1991, the same year that Biotech was founded. You're going to hear that ten years before OP-1 Implant was approved -- remember in '01 -- a man named Aaron Weston from Louisiana had over 17 surgeries to repair a leg that was shattered in a car accident. On the very day that his leg was scheduled to be amputated, Aaron's surgeon told him about a clinical trial that was testing a potentially revolutionary new cure called OP-1. Aaron became the first person treated with OP-1. Within a month his X-rays showed that his leg had begun to heal. Today, over 20 years later, the bone is strong and he has his leg. OP-1 saved Aaron's leg and changed his life.

You're going to hear that these patients came to Biotech sales meetings and told their personal stories of how OP-1 changed their lives. The men and women who worked at

Biotech, including the individual defendants here, had reason to know that OP-1 was a game-changer. Biotech's dreams for the product and the dreams of these sales managers were vivid and real. Biotech did not develop OP-1 to make a short-term profit; Biotech's commitment to OP-1 was long term and expensive.

You heard a lot about sales goals and money from Ms. Winkler. Quietly, but you heard it. The indictment claims that the goal of the criminal conspiracy was to make millions of dollars through fraud. On that subject, I'm just going to say that Biotech, like every other business in America, did pay attention to sales and revenue, and it rewarded hard-working, successful and compliant sales reps with commission payments. It also established sales quotas for field sales representatives.

Biotech's parent, Stryker Biotech, is a public company with shareholders to represent and employees to pay. But none of that is criminal. It's not even unusual. Ms. Winkler unfairly ignores that Biotech's primary mission during the supposed conspiracy was not to make quick money; it was to complete clinical trials with OP-1 and secure premarket approval. The company knew that that would take a long time and come at a huge price. In fact, during the mid to late 2000s, Stryker Corporation invested hundreds of millions of dollars developing OP-1 and researching other products it hoped

to make from BMP7. But that was okay. Stryker had a dream and was willing to wait.

Let's talk about the FDA for a moment. Clearly the FDA is a very important government agency to all of us. Its primary mission is to promote and protect the public health. It does have responsibility to make sure that our food is safe, our drugs and devices are both safe and effective. It does review and approve medical devices for manufacturers like Stryker Corp. and Biotech, and it regulates how those manufacturers market those devices. I will tell you that while the FDA's a government agency and the Stryker company's a business, they share a common goal of helping patients. In short, Stryker Biotech -- and I would add, these men -- have enormous and genuine respect for the role the FDA plays in this country.

But I'll also tell you that while the FDA plays that very important role -- and this is the law -- it has no authority over how any physician practices medicine or over how surgeons choose to use FDA drugs and devices. The reason for that is because doctors have to be able to use drugs and devices in ways they believe will benefit their patients because medical science on devices moves much faster than the FDA does.

Surgeons will see how a device works to treat one condition, and a drug as well, and that experience leads the

surgeon to believe that it might also just work on another condition, very often a condition not covered by the device's label. So off-label use by surgeons is not only legal but it's essential to their ability to effectively treat their patients. I don't expect you're going to hear anything different on that from the FDA or even the prosecutors.

One off-label use we're all familiar with is baby aspirin for stroke or heart attack prevention. That's just one of many off-label uses of drugs and devices we see in everyday life. In some areas, off-label use by doctors is the norm with cancer treatments, mental illness medications. A very high overall percentage of treatment is off-label.

You're going to hear that off-label use of medical devices, particularly in spine surgery, is also very common. It's standard practice. Not surprisingly, in spine surgery the technology and surgical techniques are constantly evolving and surgeons are always seeking the latest information. They learn from medical journals and from their federal -- excuse me -- fellow surgeons at professional conferences and continuing medical education programs.

But another important way surgeons learn is by asking sales representatives in the field what the latest information on surgical techniques is and how their surgeon peers are using these devices. These discussions, ladies and gentlemen, are good. They enable surgeons to achieve better results for

patients. It's really important for you to know that providing information in response -- in this case in response -- to a surgeon's questions, a request for information, is not promotion and it's not illegal.

So importantly, who are these surgeons and how do they make their treatment decisions? They are neurosurgeons and orthopedic spine surgeons, among the most gifted and highly trained physicians in this country. They go to college, and then four years to medical school, and then to surgical internships, and then to five- or six-year surgical residencies in their specialty. And even then sometimes to one or two more years in advanced fellowships in spine procedures.

These surgeons write and edit articles for major scientific journals; they perform clinical research; they hold leadership positions in the American Academy of Orthopedic Surgeons and the North American Spine Society; some of them teach at major universities; some are in our communities, they're community-based surgeons; and some are renowned clinicians who have practiced for decades and perform hundreds of surgeries every year.

These surgeons include men like Dr. William Caton. If you just look at your monitor for a second and just see, as you can see -- well, let me just -- he's the former president of the California Association of Neurological Surgeons. Right now he's chairman of the Department of Neuroscience at Huntington

Memorial Hospital, big hospital in Pasadena where the Rose Bowl is, right near LA. Dr. Caton is a nationally prominent neurosurgeon who grew up in Newton, studied at MIT. He has performed over 10,000 brain and spine surgeries.

So what's a neurosurgeon? Well, you hear people say, "He's no brain surgeon," right? Well, Dr. Caton is a brain surgeon. He's both a brain surgeon and a spine surgeon. He's going to come in here and testify before you about the incredible results he has achieved in over 200 spine surgeries on sick and elderly patients in California with the OP-1/Calstrux combination.

These surgeons also include trauma surgeons like one who's going to come in and tell you that he chose to combine Calstrux and OP-1 to fill a three-inch void in his patient's crushed leg because using OP-1 according to the label would not have provided enough total product. Another very impressive trauma surgeon will testify that he used OP-1 off-label to heal soldiers injured in Iraq and Afghanistan whose only alternative was amputation.

Now, it is important to note that Dr. Caton and other surgeons, they didn't always choose to mix OP-1 with Calstrux. It wasn't reflexive; it was thoughtful. They made the decisions about what and how to mix based on their individual patients' needs. Before Calstrux was introduced in 2004, there were over 100 other bone void fillers on the market. So you

remember that substantially equivalent to Calstrux -- substantially equivalent to others -- Vitoss is one you'll hear about and you'll hear about others. Those, for years, have been providing that structure, or scaffold, that the stimulator product, the bone, or the OP-1 or the InFuse stimulated.

Even after Calstrux was on the market, over half the time surgeons didn't use Calstrux with OP-1. They made a choice. They would choose instead to combine OP-1 with other things: bone chips, bone marrow and blood, and other bone void fillers like Vitoss. It's safe to say, the point is, that surgeons, they know their own minds. They make their own decisions based on what they think is best for patients.

So -- I'll take a quick drink.

What I've tried to do so far is to give you what we believe to be the very important factual context for this case. It will be proven by lay and expert witnesses as well as documentary evidence.

So what is the government's case? And you're going to have the indictment back in the jury room. What does the indictment say is the prosecutor's main allegation? The prosecutors say that the defendants manipulated, lied to and defrauded surgeons. They tricked surgeons into using OP-1 and Calstrux together. The prosecutors also say that the defendants formed a criminal conspiracy to target and defeat their agency, the FDA, through lies, trickery and deceit. But

they also say that they did it mainly by manipulating the surgeons, all right? So let's step back and ask: Which surgeons did the prosecutors Biotech, Bill, Dave and Jeff, supposedly trick? I'd like you to look at your monitor for a moment.

The indictment specifically identifies only seven surgeons: Drs. H, P, C, D, M, I, and R. Now, you would think that before bringing these very serious criminal charges bringing us all together, the prosecutors would have taken the time to interview these seven surgeon victims, right? They would have wanted to confirm that the supposed victims were actually victimized, right?

Well, apparently not. Incredibly, before hauling these defendants into court on criminal charges, the prosecutors and their hefty core of investigative agents never interviewed even one of these supposed victim surgeons. They never spoke with them. They never even tried to speak with them. They took two years before this indictment to investigate. They could have taken longer. There was no deadline to meet.

They had the awesome power to subpoena to the grand jury any person, including surgeons anywhere in the country. They had the time to compel dozens of people to testify before the grand jury, but not these surgeons. They had the time to pore over millions of pages of emails and other documents and

cherry-pick -- the ones Ms. Winkler had in her hand -- a handful of emails, isolate them and present them in the most negative possible light. But apparently, they had no time to ask the surgeon victims: "Were you tricked?"

Ladies and gentlemen, they may not have talked to the surgeons, but we did. And because of that, you're going to get to hear the surgeons' side of the story. Let's stop and think about this for a second. The defendants in this criminal fraud case who, as the Court will tell you, have no burden to do anything at all and are entitled to just look the prosecutors in the eye and say, "Prove it," are the ones who will bring the supposed victims of this fraud here to testify.

Why will that testimony be important? Well, because these surgeons, whose full identities you're going to have, and who are going to take that witness stand will tell you three things: The defendants did not lie to them; the defendants did not deceive them; the defendants did not defraud them in any way.

Ladies and gentlemen, the key question teed up by this indictment is whether the defendants intentionally manipulated and tricked surgeons into using the OP-1/Calstrux combination. The answer to that is no.

Now, let me talk just briefly about the relationship between those highly skilled and trained surgeons and medical device sales reps. You're going to hear over and over in this

case that the key to a sales rep's success is building a relationship of trust with the surgeon. You're going to hear that from sales reps and surgeons alike. Sales reps work hard to develop trust with their surgeons. Every interaction with a surgeon's an investment in the rep's career. A sales rep's relationship with the surgeon is even more important than his or her relationship with their own company, like Biotech.

Use your common sense. Does it make any sense for those Biotech reps to intentionally lie to or trick their surgeons? These surgeons are smart. They are not easily fooled. They're specialized, in a small, tight-knit community. They all talk to each other. There aren't that many of them. Lying to even one of them is professional suicide.

Also, OP-1 was a long-term play for this company. Biotech fully expected to get the PMA approval Ms. Winkler mentioned, and the rep's expectation was what -- they'd be calling on these same surgeons for years to come. Would they put all of that at risk to make a short-term buck? No way.

So apart from discussions with sales reps, how did surgeons learn about the prospects for mixing OP-1 and Calstrux together? Now, the history's important. For many years before these products came on the market, surgeons were combining other substances to create these bone grafts, malleable bone grafts, that had each of the necessary elements: cells, stimulation, structure. Surgeons mixed or combined natural

graft materials like bone chips and cadaver bone, as well as synthetic materials like these bone void fillers. So that was all going on before OP-1 and before Calstrux.

But there also was a body of scientific literature going back to the 1990s documenting and endorsing this practice. You're going to have all these articles. These are scientific articles during the 1990s and the 2000s. In fact, this document -- this document right here that you're going to have. I'll just hold it up -- shows that by 2006 there were over 800 -- 800 -- peer-reviewed -- that means physician-reviewed -- journal articles written by surgeons featuring OP-1.

The articles showed that combining graft materials -- the combining of them, mixing them -- was the standard of care. That was the surgeons' standard of care. The article shows that OP-1, and later the OP-1/Calstrux combination, produced good results. Look here. One more. I'll just show you particularly. Remember Dr. Urist, the scientist at UCLA? Well, he wrote an article in 1983 that said that tricalcium phosphate -- which Calstrux is made from. Calstrux doesn't come on the market for another, what, 21 years -- was a promising delivery system for bone morphogenetic proteins like OP-1. And again, OP-1 was nowhere to be seen yet either. Back in '83 this Noble Prize person who was recommended is saying: Listen, tricalcium phosphate and BMPs could work well together.

So now let's step back. And I'm going to get now to where -- what I call -- well, it's the government's allegations -- I see it as a grab bag of disconnected government allegations, all right? So what is it? We see three things: alleged affirmative misrepresentations, supposed failures to disclose information, and then they talk about off-label promotion of misbranding.

So what are some of the -- in the first category -- allegations about, you know, the misrepresentations? Ms. Winkler says sales representatives would hold out to these surgeons a ball of either OP-1 and Calstrux, or maybe even just Calstrux, and say it's all OP-1. Do you know what's interesting? You don't have to look any further than the indictment itself at another allegation. Do you know how ridiculous that is? Probably their main off-label promotion allegation is that we suggested that surgeons mix the two of them. So how can it be fraudulent, how can it be tricky, how can it be intended to defraud a surgeon for someone to hold out and say it's all OP-1?

I'm just going to show you a quick graphic on one of those mixing instructions. Look here. This is one of the many that Ms. Winkler said the company was giving out to defraud surgeons. It says right -- it shows right in there -- obviously, their mixing instructions. Two products: OP-1 Putty and Calstrux, okay? So it's just entirely inconsistent.

Also, these products, they come in separate packages, separate boxes, you know? Calstrux: It's kept in the stockroom at room temperature. OP-1: It's kept in the refrigerator. Invoices you're going to see plainly reflect that OP-1 and Calstrux are two different products, and they're being identified as such on invoices going to the surgeons' hospitals. Fraud? I don't think so.

Another one that she doesn't mention that's prominent in the indictment is the defendants supposedly told surgeons that HDE approval, which is what the OP-1 products had, were a stepping stone to premarket approval. Now, first of all, this is the sticker that's on the side of the OP-1 boxes. It shows that they're humanitarian devices. They're not PMA-approved. So the surgeons had them and knew. But also, Biotech and its employees obviously did view HDE status as a stepping stone to PMA and they were shooting for it. But they did look at it as one step towards it. There's nothing fraudulent about them saying that. Now, Ms. Winkler talks about -- says it's fraudulent because the company said Calstrux was an extender, or a carrier, for OP-1; that Biotech was fraudulently telling surgeons that Calstrux was either part of OP-1 or that there was no basis for saying it.

I mean, clearly these are two different -- they're two different products. Surgeons understood what they were -- structure, scaffold, stimulation -- and what they were not.

They weren't deceived in any way if and when the company said, "Listen: Surgeons are using the product, Calstrux, as a carrier or an extender for OP-1."

Now, the second type of alleged fraud that the prosecutors allege is that the defendants tricked doctors by what they didn't say; in other words, the defendants supposedly committed fraud by failing to disclose information. Well, what information are they talking about? The indictment talks about -- says that we didn't disclose that mixing -- the OP-1/Calstrux combination wasn't approved at the FDA.

Well, we did tell surgeons that information. How did we do it? The FDA-approved labels -- and you're going to have them in the jury room -- for OP-1 and Calstrux, they accompany every box -- tells surgeons exactly what the indications are and what they're not. That's one way.

Another allegation: The government says that OP-1 -- that we never said that OP-1 and Calstrux has not been clinically tested in humans. Look at the OP-1 Putty label. It says that the product hadn't been clinically studied in humans for its approved indication. Also, on Calstrux, surgeons knew what a 510(k) product was, a substantially equivalent product to another one already on the market, and they also understood that in that case there weren't clinical trials of humans that went into it. It's kind of a fast-track approval. Surgeons knew that.

Now, the biggest allegation about what we didn't say, the government says we failed to tell surgeons about adverse events including -- and you'll have it in the indictment -- inflammation, drainage, impaired wound healing. Well, first, the company -- and you'll see the evidence -- diligently tracked adverse events. And only 63 adverse events were reported in over 10,000 total surgeries with the OP-1/Calstrux combination. In any event, the prosecutors will concede again they cannot prove the combination caused any adverse events, and the very definition of adverse events, it doesn't mean that the surgeon says, "I think it's the product." And it doesn't have to be a serious adverse event; it could be something very minor. So that's one response.

But another one is we did tell surgeons over and over again about the possible adverse events associated with these products. How did we tell the surgeons? Well, again, through our FDA-approved labels which were -- I'm not going to show it now and slow it down, but it shows that -- it shows the possible adverse events, and they're the same adverse events that the government says we failed to disclose. They're on the label for the surgeon.

How else did we tell surgeons about the adverse events? Well, the company put out marketing materials. And those materials, like the label, clearly disclosed the same types of adverse events that the prosecutors say were not

disclosed. How else? The company reported to the FDA every adverse event associated with OP-1 used alone, and also reported every adverse event when OP-1 was used with any other product, including Calstrux.

Biotech sent reports which met -- what you'll understand to be here MDR -- medical device reporting requirements to the FDA. That information, the information from those reports, was posted on the FDA's website for surgeons to read. On other adverse events that didn't meet that MDR standard, the company reported all adverse events, as they were required to do, to the FDA in their annual reports. You're going to have those reports to review.

How else did we disclose? Well, after learning of a handful of adverse events in '05 -- remember, Implant: '01; putty: '04; Calstrux: '04. Well, in '05 we got a handful of reports, seven, of adverse events. Not serious adverse events. And so the company decided to send out to surgeons a special letter: Forget the label. Forget the reporting. Let's send a "dear-doctor" letter.

Can we see it, please?

And here it is: September 7, 2005. "Dear valued customer, over the past few months we've become aware of instances where Stryker TCP Putty" -- that's the early name for Calstrux -- "appeared to have inappropriately migrated into subcutaneous tissues. The majority of these instances have

occurred when Stryker TCP Putty has been used in combination with other products in distal extremities where there appears to be difficulty in containment of the TCP product with surrounding tissue."

So who did they send it to? Well, they sent it to every known user, over 700 -- every known surgical user of Calstrux. No disclosure? Yes, disclosure. The prosecutors cry fraud -- Ms. Winkler spoke about it -- based on the company's failure to send another letter in February of 2006.

Yes, it is true that in February 2006, just five months after this letter was sent, the company considered sending, but did not send, another letter to surgeons. Why? Criminal fraud? Mr. Heppner, Mr. Whitaker, Mr. Ard engaged in criminal fraud? No, not at all. There was a consensus decision at headquarters in Hopkinton not to send a letter at that time. Why? Well, mainly because another letter had just been sent six months earlier, and Biotech had reason to believe that the adverse events were caused by a few surgeons' techniques.

Who made the decision? Mr. Heppner? Mr. Whitaker? Mr. Ard? Someone else who's alleged to be a criminal coconspirator? Not at all. You're going to hear that Beth Staub was involved in that decision as the head of all regulatory; Bernadette Alford. She's going to be the second witness; Judith Sernatinger, VP of quality assurance; John

Houghton, the first witness, VP of marketing and sales; Sau Gee Yung, the head of operations; Michael Silverman, VP of clinical affairs; Dean Falb, VP of research and development. The brain trust at the home office made the decision: "Not yet. Not now."

Now, the emails that Ms. Winkler had from the sales managers, whether it be Mr. Heppner or Mr. Whitaker, they don't prove fraud. Why not? Well, first, everyone at Stryker Biotech, including these people, strongly believed in the patient benefits of OP-1. And that's important not to lose sight of, okay? Yes, Bill Heppner was outspoken and supportive about the sales effort. He's a great athlete; he's competitive; he was supportive. He was a warm-blooded participant in the whole sales effort.

Bill fully supported sending another Calstrux letter to the people who mattered, the surgeons, even then when it wasn't sent, as Ms. Winkler said, but he was concerned that sending a letter to institutional review boards, to administrators at hospitals -- some might be surgeons but most not -- that might cause an overreaction that wasn't warranted given the limited adverse events that had been reported up to that time.

But it's important to note Bill wasn't the decision-maker. None of these men were the decision-maker of whether a letter would be sent to the IRBs, and he never

expected it to be.

The prosecutors harp on in the indictment -- Ms. Winkler read them -- Bill's emails. But the emails don't prove fraud. What do they prove? They show that Bill is openly telling the decision-makers at headquarters in Hopkinton -- Bill's up in Chicago, in the field, all right -- what he believed the impact on IRB administrators would be if they received a letter about Calstrux. That's not fraud.

Each individual in the process played his or her role appropriately. It was a robust process, as you'll see. The sales managers offered their perspective, but it was the regulatory people, including the second witness -- the first witness too -- and others at headquarters who are not alleged to be criminal coconspirators who made that consensus decision.

So what was the outcome of that process? Well, the company came up with a plan to better and more fully assess the adverse events. What was the plan? Ms. Winkler mentioned part of it. Mr. Houghton's training in the beginning of March, that was part of it. Another part was the regulatory group was to conduct, and did conduct, what's known as a health hazard evaluation to better understand what was happening with the products. Headquarters was going to continue to assess whether another letter -- remember the September '05 one? Whether another letter to surgeons was warranted.

What did the company conclude after that process?

Well, they decided ultimately to do more than just send a letter. And you're going to hear about it. It's incredible. A criminal fraud by not sending a letter in February or March. Here we are in the summer, same year. What do they decide to do? Well, after this regulatory letter assessment, the company decided, proactively, voluntarily on its own, to advise the FDA of a Calstrux label change it was considering, about which it wanted to send another letter to the surgeons.

Here's the letter that Biotech sent to over 700 surgeons when it followed through and changed the Calstrux label. So they complain about not sending a letter in March? Well, here they are, they're changing the label and sending this label to doctors, "Important safety alert: Calstrux. Calstrux should be used as directed. Do not exceed total liquid advised or overfill the defect site with Calstrux. The volume of Calstrux used should approximate the size of the defect. In addition, Calstrux should not be used in combination with other products. Adverse events, including localized induration, swelling and inflammation, et cetera, are possible."

Now, the label change, let me just tell you, that's what they call a precaution. This is a conservative step, a conservative company saying: Surgeons, you're choosing to use Calstrux with OP-1. We're going to put on that label -- because we have some reports, you know, not serious adverse

events but -- not a lot, but some. So we're going to put a precaution on the label. The FDA edited that letter's content and approved it before it went out.

We didn't disclose to surgeons? Yes, we did. Just -- you know, you're going to hear some evidence. There's a phone call in August. There's ten people on the phone from the FDA and one for -- excuse me -- and six from Biotech and so I just want to make one note. You know, the whole complaint here is, gee, the FDA didn't know about the combination and we weren't telling them enough.

Right on that the company volunteers, Listen: Calstrux is being used 90 percent of the time with OP-1. Yes, it's a bone void filler but it's used a lot. These surgeons are using it a lot as a carrier and extender. Is that evidence of a conspiracy? I don't think so. They're talking to the FDA.

These, ladies and gentlemen, were conservative steps by responsible people. Any delay from February to August was not due to a regulatory person's diligence -- was due to a regulatory person's diligence, not to the actions of alleged coconspirators.

Let me put up something here that I think says, you know, a lot about the government's case. It's a little crooked. It won't be up long.

So listen, this is the way the indictment is

structured, all right? They say that in Hopkinton, Mr. Philip, Biotech, the president -- he's a defendant in the indictment. He's an alleged coconspirator. The other alleged coconspirators and defendants here are Bill Heppner, Jeff Whitaker and Dave Ard.

Bill was the national sales director back at this time; Jeff and Dave, they were regional sales managers. They're all out in the field, all right? Dave is out west; Jeff's southeast; Bill is heading it up and he's in Chicago. This man named Peter Murphy, he's the northeast manager; Ryan Denny, midwest manager, all right? So Denny and Murphy: coconspirators, says the government, not indicted. And down here lots of sales reps, criminal coconspirators, but not indicted.

But the thing that really doesn't make sense is on a case where you're saying, gee, the company failed to disclose, failed to talk to surgeons, failed to tell IRBs important information, it's these people who were responsible for making those decisions. They're -- as far as the government has alleged, they're innocent, all right? They haven't done anything wrong. They're not criminal coconspirators like Mr. Philip and everyone down here out in the field, and yet these are the people who are making the decisions about do we send a letter in February or March? You know, what do we do vis-à-vis the FDA? What do we do vis-à-vis the surgeons in

terms of getting them more information? The point of this is that the government's conspiracy allegations don't make any sense. And we're going to revisit this at the close of the case.

So just a note. I mentioned IRBs. We didn't think it was a big part of the case but, you know, I think what Ms. Winkler is saying, we failed to disclose to IRBs adverse event information too. Well, we didn't fail to disclose adverse event information to IRBs. Remember, IRBs play that role at the hospitals, where surgeons work. The big thing about IRBs is their main relationship, it's not with the manufacturer. These are administrators who are gatekeepers to some extent, but they get to oversee what products are used at the hospital. The main relationships IRBs have are with surgeons; they're not with the manufacturers.

The law? What does the law say about what manufacturers have to tell IRBs? Well, the law requires that companies report -- and this makes sense -- to IRBs only those adverse events that happened at the IRB's hospital, all right? Not every adverse event that comes in from Australia or Europe or California, just those that happen at the hospital. And do you know what? We did. And the evidence will show we disclosed to hospital IRBs every serious adverse event, which is what the requirement is, that happened at their hospital. Also, you know that August 2006 letter the company sent to IRBs

in October of '07 saying they should have the letter that shows the label change on Calstrux? Also, despite the fact that we don't have a big relationship with IRBs, you're going to see evidence of a lot of things we did give to -- send to -- the IRBs about OP-1 and about Calstrux.

All right. Just one other point about adverse events. Ms. Winkler mentions you're going to see that there was even excess bone growth with some patients. Well, there were a couple. But just think about that. That's what OP-1 does. It grows bone. They say it doesn't work? It works. That's the adverse event? If that's the adverse event -- I mean, I think that tells you a lot about this case. And also, the label doesn't mention that's a possible adverse event? Yeah, it does. It mentions it as a possibility even when two units are used. And as you'll see, sometimes surgeons decided to use more than two units. Why? They're on a big surgery where they wanted more stimulation. So if that's the adverse event evidence, I think it tells you a lot.

So let me talk about the third category of government allegations briefly. And this is a little bit heavy but I'm going to try. In the third category, the government says the company engaged -- Count 7 to 12, just against the company, as Judge O'Toole said -- in off-label promotion.

The government here is trying to equate communications by Biotech with surgeons about the OP-1/Calstrux combination

so-called off-label promotion with fraud. Judge O'Toole's going to instruct you that the -- he already did, actually -- that the misbranding charges against Biotech require that prosecutors prove not only misbranding on Counts 7 to 12, but also, that the company intended to defraud -- same theme -- surgeons or the FDA.

As you'll hear during the trial, the defendants provided information in response to physician requests. Again, no -- FDA: No oversight over the surgeons. Surgeons can ask questions; manufacturers can answer them. That's not off-label promotion.

But even when off-label promotion does occur -- in other words, you don't wait for the question or you think there's a question, but the prosecutors or the FDA might disagree -- that's not felony misbranding, which the prosecutors have charged here. 7 to 12, felony misbranding. Not down here, okay? So it's not felony misbranding unless they also show that the company intended to lie to or deceive surgeons.

All right. On this subject, Ms. Winkler held up a couple of slides. And I don't know if they're still over here but I would be happy to hold them up again. You're going to see them with the first witness, John Houghton. And I think that their presentation on this is misleading.

Now, in March 1, as you'll hear, 2006 -- remember when

the letter didn't go out and they decided to do some training and the health hazard evaluation, et cetera -- John Horton, who is going to be the first witness, conducted a very conservative training of the sales force as part of Biotech's effort to address the fact that a few surgeons had reported adverse events in surgeries involving the combination.

On that first slide that Ms. Winkler kind of held up, it says on it: Do not promote off-label, do not do this, do not do that, do not do the next thing. That slide -- all our view -- just -- and we'll get to the witnesses -- proves only that Biotech was responding conservatively, responsibly to the reports of adverse events by telling reps: Don't engage in off-label promotion.

Again, off-label promotion is just a regulatory promotion. It can be a misdemeanor, criminal violation. It's not what's charged here. What's charged here is misbranding with an intent to defraud, to deceive surgeons.

The second slide she held up, it says on them, the top of it -- you'll have it tomorrow -- "Consequences of off-label promotion." It probably was not created by John Houghton, someone else who worked on the slide deck with him. It's unclear, at least to us, who drafted it. Probably somebody in regulatory at Biotech in Hopkinton, but definitely not a lawyer.

Now, as Ms. Winkler says, it uses some big words about

consequences, right? The slide says, "Criminal misbranding prosecution is a possible consequence of off-label promotion." Now, it's not clear what the person who drafted the slide intended to convey, but off-label promotion alone is only a regulatory violation. At most, a misdemeanor. We don't have any of those charged here. It's not what's charged in 7 to 12 in the indictment, the felony misbranding.

As Judge O'Toole will tell you at the end of the case -- and he already did mention it -- to prove felony misbranding the prosecutors have to prove beyond a reasonable doubt that Biotech acted with an intent to defraud or they're to be found not guilty. The evidence will show in this case that Biotech never acted with that criminal intent, and for that reason alone we're going to ask you on Count 7 to 12 to find the company not guilty.

Now, on this subject of supposed off-label promotion, they've got a laundry list of allegations. Again, vague, sometimes inconsistent allegations. But they don't -- they don't even prove simple regulatory violations much less criminal fraud. Let's just review a few of them. Let me just see the ones that she mentioned. I think Ms. Winkler mentioned Biotech trained the representatives how to mix the combination. There will be evidence that there was training and demonstration, or showing reps what surgeons were doing.

Now, our answer to that is it would have been

irresponsible for the company to put its reps out in the field when the standard of care was mixing without telling them that, without people talking about the obvious fact that surgeons were choosing to mix OP-1 and Calstrux. But in any event, mixing, or talking about mixing, doesn't equate with fraud and doesn't prove Count 7 to 12, which is felony misbranding.

Also, Ms. Winkler talks about, Oh, gee, they've got commission-based pay and quotas. Well, as many of you might know, commissions are standard in a lot of sales industries, and quite standard in the medical device industry. Paying a sales rep on a commission basis is not criminal. It tells you a lot about these allegations. Giving sales reps quotas, that's not criminal either.

Ms. Winkler mentions, Oh, the company -- even though the label said "two units per patient," the company promoted one unit to surgeons instead of two units. Well, the first response: It's ironic to me that the prosecutors would suggest that this company that was trying to make gazillions of dollars tried to sell fewer units per patient and make less money.

But the big answer is: It's the surgeons who were using to use one unit when the size of the void calls for it. Dr. Caton will tell you: "If I have a big void that needs to be filled, I'm going to use two. If you've got less, I'm going to use one." It's the surgeons. That's why surgeons get to do what they want; why the FDA doesn't regulate them.

Ms. Winkler mentions discounted pricing like it's a bad thing, all right? She says the products were tied together and discounted. First, they weren't tied together. But the company did give discounts to hospitals they were working with for a long time. Hospitals were trying to lower the cost of healthcare, and Stryker was going along. That doesn't show off-label promotion.

Let's talk about the mixing instructions. And there were a lot. So the company's response on that is surgeons wanted to know what is another surgeon doing? What is making sense? What is working? And that question is out there. It's out there throughout the conspiracy. So the company at times did give mixing instructions.

Now, were those fraudulent? Were those intended to trick the surgeons to harm the patients? No, definitely not. Those were the reps' best efforts to convey information about what was working, what wasn't, what proportion do you use the OP-1 and the Calstrux in? Do you mix in blood? Do you mix in saline? Do you mix in bone chips? What do you do? What makes sense? Is that fraud? No. It's an effort to help the surgeons help the patients.

Now, fraud on the FDA. The government says -- well, how do they say we perpetrated a fraud on the FDA? Well, they say that we conspired to target the FDA for defeat, lies, trickery and deceit. But what they then break it down into

saying is that -- they say that the FDA conspiracy claim rises or falls on whether the evidence supports a criminal fraud scheme against the surgeons.

I've already addressed that. There was no fraud on the surgeons. But also, use your common sense. The defendants had no reason to lie to the FDA. Biotech wanted to have, and needed to have, a good relationship with the FDA because that was important to its effort to get PMA approval for OP-1.

But, you know, I do have to -- you know, the indictment says, and Ms. Winkler touched on it -- do you know what one of their big allegations is? In terms of this fraud, they say in August when we did that label change on Calstrux, the precaution, and sent out the letter to surgeons -- remember, they said, Oh, you're terrible for not sending a letter in February and March? Well, now in August we send one and we tell about the label change.

Do you know what they say? "Fraudulent lulling of the FDA into not investigating you." Fraudulent lulling. They say we knew surgeons don't look at labels. Surgeons don't read "dear-doctor" letters. It is ridiculous. It is ridiculous. That is what the FDA conspiracy is. The government says we didn't do enough in March by not sending a letter; we send one in August, fraudulent lulling. It's ridiculous.

Remember I told you how this case got started, when Stryker Biotech went to the FDA during the height of the

supposed conspiracy and said, "We have a problem we want to report to you"? If the company really was defrauding the FDA, why would it make reports about its own employees' IRB misconduct? Why would a guilty, criminal-minded company invite the FDA into its own house in Hopkinton? A company trying to defeat the lawful functions of the FDA would never do that.

In addition to the FDA disclosures, in early 2008 Biotech gave statements it took from employees about their IRB forgeries to these prosecutors. The prosecutors had suggested to the company that they wanted the statements and that it would help the company to give them. Shortly thereafter, the prosecutors threatened the former employees -- the ones we reported, or the conduct of whom we reported to the FDA -- with criminal charges. Ultimately, you're going to hear --

MS. WINKLER: Objection, your Honor.

MR. O'CONNOR: -- those former employees.

THE COURT: Excuse me. I'm sorry. There is an objection.

MS. WINKLER: To the "threatened."

THE COURT: Well, no. Go ahead.

But as long as we paused, Mr. O'Connor, let me remind you of the time.

MR. O'CONNOR: Yes. I'm just about done, your Honor. Thank you. I appreciate it.

THE COURT: All right.

MR. O'CONNOR: Ultimately, the former employees cut deals with the prosecutors, agreeing to plead guilty to criminal charges and cooperate against the company. Under their plea agreements, the former employees are now hoping, you're going to hear, to escape prison terms and financial penalties, not to mention a trial like this one, in exchange for their testimony in this case.

When they cut their deals, these former employees knew that they would get no credit for talking about misconduct the prosecutors already knew about from our client, from Biotech, forging of IRB signatures. They knew they had to help the prosecutors make a new case, so here we are.

You will hear and see these former employees whose sentencings the prosecutors have asked to be delayed -- delayed -- until after this trial, do their best to earn the prosecutors' recommendations that they not go to jail.

Obviously, part of your job will be assessing the credibility of witnesses. We expect Judge O'Toole will instruct you to be particularly cautious in assessing the credibility of these government witnesses.

Ladies and gentlemen, in closing, Stryker Biotech is a good and honorable company that at all times was trying to help patients, not hurt them. Biotech never would have put its business at risk by defrauding surgeons or the FDA. Biotech sales reps only gave surgeons information they thought the

surgeons wanted and would benefit from.

The evidence will show that the defendants are not criminals. They did not lie, cheat or steal; they did not commit fraud. We expect it will be several weeks before we have the opportunity to call witnesses for the defense. I would ask you to listen carefully to all the evidence that would be presented by both sides and reserve your judgment on the fate of the defendants until all the evidence is in.

At the close of that evidence, we're going to have an opportunity -- a chance -- to speak to you again, and at that point we're going to discuss why the evidence is wholly insufficient to prove beyond a reasonable doubt that Stryker Biotech is guilty of federal felony criminal conduct. Indeed, as I said when I began, the evidence will show that this case is nothing more than a misguided prosecution, a gross injustice to these defendants. For that reason, we will ask you to return a verdict of not guilty.

Thank you very much for listening so carefully and, again, thank you for your very important service as jurors.

THE COURT: Jurors, we'll take a short recess before we continue. Let me just ask -- I'll probably be reminding you of this constantly during the case. It's important that you reserve any discussion of any of the issues in the case until your formal deliberations. So even though there may be some temptation to talk about what you've heard from people now or

as the case goes on, please stay away from the substance of the case in any of your casual conversations during our recesses, all right?

So we'll take a short recess. We'll resume about twelve o'clock and continue.

THE CLERK: All rise. The Court will take a short recess.

(The Court and jury exit the courtroom and there is a recess at 11:45 a.m.)

(After the recess:)

THE CLERK: All rise for the Court and the jury.

(The Court and the jury enter the courtroom at 12:06 p.m.)

THE COURT: You're already there.

MR. ULLMAN: Ready to go, your Honor.

THE COURT: Mr. Ullmann.

MR. ULLMANN: Thank you, your Honor. May it please the Court, members of the jury. My name is Bob Ullmann. And along with Maya Sethi, we have the privilege of representing William "Bill" Heppner in this case.

Stand up, Bill.

Tricking surgeons, ignoring safety concerns, defrauding the FDA, these were strong words from the prosecutor. There's just one problem. None of it is true.

In May of 2005, one of the very first government

witnesses that you'll hear from, John Houghton, promoted Bill Heppner to be director of sales for Stryker Biotech, and he remained in that position throughout the time of the supposed conspiracy, not because he was tricky or conspiratorial, but because he was hard-working, earnest, and trustworthy.

And you don't need to hear that from me because you're going to hear it from the government's own witnesses. Bill Heppner is charged in six counts of the indictment: one count of conspiracy, five counts of fraud. And every one of those charges requires the government to prove beyond any reasonable doubt criminal intent, an intent, intentional violation of the law.

It's the complete opposite of the way that Bill Heppner went about his job. Call this prosecution anything you want, call it misguided, call it overreaching, or call it just plain unfair. Bill Heppner was wrongly charged. He's innocent.

A little background on Bill. He grew up outside of Chicago. In 1987, he was named as one of 20 high school students in the entire country as McDonald's All American in basketball. He played Division 1 at DePaul until, unfortunately, a congenital spinal condition ended his basketball career.

But Bill turned obstacle into opportunity. He learned a lot about orthopedics, the spine and medical devices, and

that led to a career in orthopedic and medical device sales. In fact, by the time Bill had reached his early 30s, he was already in sales management. But he actually took a step back.

In 2002, he went back to a field sales position when he joined Stryker Biotech. And he did it to join a great company that was developing and selling and marketing a great product: OP-1, a game changer in bone healing.

The entire case against Bill Heppner is built around an implausible accusation that a well-respected career medical sales device manager would intentionally trick surgeons. Medical device sales is all about relationships and trust. You see the same surgeons week after week, month after month. And the orthopedic medical community is a small world. You lose the surgeon's trust, you are toast. Career over.

Surgeons trusted Bill Heppner, and you'll see that. And Bill also had the trust of Stryker Biotech management and the sales team because he was straightforward, hard-working, and he could be trusted. And let me tell you, the accusation that he defrauded the FDA, that is ridiculous. The FDA wouldn't know Bill Heppner if they bumped into him on the street. He barely had any contact with the FDA. That accusation is made up out of whole cloth.

Let me tell you a little bit about what Bill Heppner's job was at Stryker. Because there is so many things wrong with the accusations in this case, it's hard to know where to begin.

For one thing, when you hear "conspiracy," you're probably thinking about Bill Heppner skulking along the corridors at Stryker Biotech, although I guess if you're six-foot-eight, maybe it's hard to skulk. You get my point, okay?

Well, Bill Heppner wasn't -- he operated out of his home in Chicago, 900 miles away, all right? I say that not to distance him from the company because it was a company filled with good people doing the right thing. But you have to understand when it comes to his communications, he was sending emails from 900 miles away, and he felt sometimes there was an issue that he cared deeply about for the sales force, and he had one shot. He took his best shot to send an email to make his point.

His job was challenging, but it's actually quite simple to explain: hire quality sales reps, coach them, spend time with them. Now, when you have a national sales force, that involves travel. And when you have young children, as Bill has, that's difficult. But you understand that comes with the territory, all right? And at the same time you have to be responsive to the senior management above you, and you have to be responsive to the sales force that reports to you.

The prosecution wants you to believe that Bill Heppner woke up one day -- or maybe they think he woke up every day -- and said to himself, You know what I'm going to do today? I think I'm going to defraud surgeons and the FDA, all right?

Nothing, nothing could be further from the truth. Bill Heppner did what every sales director in the country does: hire go-getters, help them meet sales objectives and other goals, hold them accountable, but also advocate on their account with the company's leadership. And nothing he did, as you will see, nothing he did was remotely fraudulent.

There's a core question in this case, it's a fundamental question: why did surgeons use so much OP-1 and Calstrux? Is it that they were deceived? Or is it that these were actually good products? And that's going to be your role: to see whether the government has proved and can prove beyond any reasonable doubt that surgeons were somehow tricked into using these products.

To answer this, you're going to hear a lot of evidence that OP-1 was a breakthrough product. You're also going to hear that Calstrux played an important role in surgeries. And you'll hear that Bill Heppner was passionate about OP-1 and his sales team. Yes, of course he was competitive. He wanted them to succeed. He was open. He was trustworthy.

But what you won't hear, what you won't hear is that Bill Heppner engaged in any fraud because it didn't happen. I'm sure you figured out already you're going to hear a lot of technical information in this case. You're going to learn a little bit about biology, surgery, government regulation. I know you'll do your best to get it down.

But what you really bring to this trial is something very different. What you bring is your life experience and your common sense. There's no expert in this world that's a match for your collective knowledge and experience. Common sense and experience are very important in helping you assess the evidence in this case. All right?

Let me give you one example. The government told you about this supposed enormous pressure that Bill Heppner and other managers were putting on the sales force, pressure where it was so intense that they somehow had to violate rules and regulations.

I'd like to show you an exhibit -- and I'll be showing you just two, but if you -- if -- you don't have out your screens -- right? And this is an exhibit, Exhibit 143. This is an exhibit that the prosecutor showed you. I'm going to read the first paragraph.

And this comes -- this comes from Bill Heppner. This is actually a count -- this is a wire fraud count in the government's indictment. "If you're getting this email, unfortunately your Calstrux numbers fell below 10 units last month. Some of our reps have put up huge numbers with Calstrux our first four months and have been able to financially benefit from it at 10 percent" -- I'm sorry -- "16 percent. We, I, need you to also start showing a northward trend with Calstrux."

"We, I, need you to also start showing a northward trend with Calstrux."

For those of you who have had bosses or who have been bosses, does that sound to you remotely like the sort of unbearable pressure, the brow-beating pressure to the sales force to the point of fraud? And I ask you what that says about other parts of the government's case.

Your common sense and experience are very important also in assessing the credibility of witnesses. The prosecution obviously is trying to present Bill Heppner in the worst possible light. Not surprisingly, there will be some prosecution witnesses who have less-than-flattering things to say about him. But you will not hear this. You will not hear a shred of credible evidence that Bill Heppner deceived anybody or suggested to any member of his sales force that they deceive anybody.

And then there are a few witnesses -- Mr. O'Connor mentioned them -- that engaged -- members of the sales force who engaged in misconduct with regard to the institutional review boards, the IRBs. You might think the three individuals here -- Mr. Heppner, Mr. Ard, and Mr. Whitaker -- that they were part of that misconduct.

Well, what you'll hear, in fact, is the three of them all played a role in dealing with the misconduct and getting rid of the very few bad apples, okay? Now, remember though,

these are witnesses, these few sales reps, they have sweetheart deals with the government, all right? They have every motive to please the government because the government's going to make a recommendation to a judge down the road about what happens to them, all right?

And you may, from a couple of them, hear different things. You may hear a few things about Bill Heppner from them that you won't hear from anybody else, all right? And I believe that Judge O'Toole will give you an instruction on how the testimony of those people must be viewed with great caution. But I don't think you'll need that instruction. If the couple people with a gun to their head say something different about Bill Heppner than everyone else, I think that you'll easily see through them.

There's something else that you're going to bring to this trial, and that's a sense of fair play, all right? The prosecutor, Ms. Winkler, suggested to you that directions from Bill Heppner to retrieve mixing instructions from out in the field, that that was somehow part of a cover-up. I'd like to take a few minutes and actually present to you what the evidence will show, all right? Not this snippet, but in a little bit broader context, okay?

In the fall of 2006, Stryker Biotech learned that a sales rep -- Chris Ring's his name -- had posted mixing instructions in a hospital in California. He posted mixing

instructions. I mean, they were the surgeon's own instructions. But still, violation of company policy, okay? Because sales reps' companies can answer surgeon questions, but they can't initiate off-label discussion. You'll hear that, okay?

And so if you post written mixing instructions, that can be seen as proactive because a surgeon that didn't ask a question could come into the operating room and, yes, they see a mixing instruction and it is proactive. They haven't asked, okay?

So what does Bill Heppner do about this, okay? And you may have different views even as to, well, you know, how bad is that? But it's a violation -- that's a violation of company policy. And Bill Heppner reacts completely appropriately.

In fact, if you put the second exhibit in front of you, he sends a letter to Chris Ring, as we -- I'll just read you a couple portions of it -- "As we have discussed many times with you and all of our representatives is that the only written documentation that you can provide a surgeon" -- "the only written documentation" -- "on the use and mixing of this document is ^ the packing insert which has been approved by the FDA."

Now, you can answer a surgeon's questions, but the only written information has to be the packing insert.

And then further down, "Please understand that this type of behavior is unacceptable and that any further violations of this type or similar to this will be grounds for further disciplinary action up to and including termination of your employment with Stryker Biotech."

Again, does this sound remotely like condoning violations of company policy -- no less fraud, right?

Okay. So then the next step, with the support of his superiors, Bill Heppner tells the sales force, get back, take back -- if you have written instructions out there, take them back, all right? This is what the prosecutors call a cover-up, okay? Now, think about that, all right? You keep those written mixing instructions posted out there, you're violating company policy. You tell the sales reps to take them down and bring them back, you're engaged in a cover-up. I mean, how do you win with that logic? I mean, what kind of fraud is that?

Briefly, the prosecutor also mentioned an email in which Bill Heppner -- Bill is advocating against sending a letter about Calstrux to these hospital IRBs. What the prosecutor didn't mention to you is in that very same email, which you'll see during the trial, I'm sure, in that very same email, Bill Heppner says that he has no problem sending a letter to every surgeon who has used the product, okay? Any one of those surgeons is free to tell their IRB. Some might feel obliged to tell their IRB. Some were members of IRBs.

I mean, as evidence of fraud, that doesn't even begin to hold water.

The long and the short of that email is simply this: As Mr. O'Connor told you, in the fall of 2005, several months earlier, the company sent a letter warning surgeons of possible adverse events from Calstrux. It sent it to every surgeon it could identify who had used the product. Now it's five months later, it's early 2006, there are a small number of reported adverse events. The company's trying to decide, are they going to send a letter. And there's a separate question. Well, if you send a letter, does it go to all the surgeons or does it go to the hospital IRBs? The headquarters wants to know -- people at headquarters want to know, what does the sales force think about this.

And Bill gives a heartfelt response. He articulates in one email the sales force position. And he says this: Institutional review boards, they don't even regulate Calstrux. They regulate OP-1, the bone healer, all right? They don't regulate this Calstrux product. And if they get a letter warning them about Calstrux, you're going to have one of two reactions. Either they will be confused or they will assume the worst, right? They're going to assume there are problems, not just with Calstrux, but they're going to assume that there are problems with OP-1, the product that they regulate.

The long and the short of this, as Mr. O'Connor told

you, is that 900 miles away from where Bill Heppner is in Chicago, the company's regulatory personnel, the senior management, decide it is not the right time to send a letter. In fact, not the right time to send a letter to IRBs or surgeons for completely legitimate reasons.

So what is the government saying here? All right? A company can't ask its employees for their honest opinion about things? I mean, honest feedback is not fraud, all right? Email has changed how we communicate. It's incredibly popular because it's spontaneous. We've all hit the "send" button and thought, You know what? I could have phrased something a little bit better. We've all been misunderstood. Bill Heppner was open. He was earnest. Sometimes he wore his heart on his sleeve.

And you know what? If down the road prosecutors and agents look at every single email you ever sent and they just pick out portions, misleading portions of emails, you know what? Maybe that's not the best way to be an employee. But let me tell you something else, all right? That's precisely why people at Stryker Biotech trusted Bill: because he was open, he was candid. There's nothing -- and most importantly, there is nothing in any email that you will see that suggests that Bill Heppner engaged in fraud or that he had any criminal intent. Nothing. All right?

Already I'm hoping you see that a couple of the

government's accusations in this case don't quite add up. They tell you that somehow there's a fraud going on. Let's confuse the surgeons. Let's trick them into thinking that OP-1 and Calstrux are all one product. Oh, but at the same time, let's send them instructions on how to mix OP-1 and Calstrux. Clearly they're two different products.

The prosecution told you about supposedly hiding adverse events. Turns out that they're on the label.

The defendants in this case have answers to every accusation. But there's something important I have to say about that. This is a criminal case. It involves our most basic liberties. And in a criminal case in these United States, defendants and their counsel don't have to do anything. All optional. Burden from the start to the finish rests on the government to prove its case beyond any reasonable doubt. And that is fundamental to our system of justice.

A little bit about FDA regulations, all right? And I wish -- I really wish we didn't have to get into them. And in a way we don't because it's a fraud case. It's not a case about regulations. But the prosecutors, I believe, want to take regulatory issues that are complicated, and even, as you'll see, to the FDA, and turn it into a fraud case. So there are three things you do need to know about the FDA's regulations.

One, surgeons can use devices off label, all right?

They are free to do what is best for their patients.

Two, sales reps can answer questions that are initiated by surgeons about off-label use.

And three, which is related to one, of course, the FDA does not regulate the practice of medicine. It doesn't tell surgeons what approved products to use, how to use them, whom they can ask for guidance, who can be in the operating room, how to educate themselves to get the best results.

And let's give the FDA credit for that. The FDA recognizes that surgeons are well educated, they are well trained. They are specialists. They are the decision makers. It's your health and your family and your friends' health that's at stake here, and the FDA recognizes that's what's most important.

I mentioned earlier that the entire accusation against Bill Heppner, that someone in his position would engage in intentional trickery of surgeons and the FDA, that it's implausible, all right, for the very reason that deceiving surgeons is a career-ending move.

But there's a second reason why this makes no sense. And that's because the surgeons' interests and the interests of Bill Heppner and other sales force members were aligned. It's accurate information that leads to better-informed surgeons, not deceptive information. It's accurate information that leads to better-informed surgeons and that leads to better

patient outcomes and that leads to more use of a product, more sales, and yes, more income for people that are selling the product.

And if that chain is criminal, you might as well indict most of the American economy. Bill Heppner had a cardinal principle. He believed that the mission of the Stryker Biotech sales force was to help surgeons get the best results: Know your products. Be there when the surgeon wants you. Answer surgeon questions. You're not a potted plant. You know your products.

And 90 percent of the use of these products, as you will hear, was off label. And nothing wrong about that. That's a surgeon's choice. So accurate answers to surgeon-initiated questions involve off-label use. But on label, off label, the operating room, the seminar of the nation's best medical schools, wherever it is, there is nothing fraudulent or deceptive about helping surgeons do their jobs.

Bill Heppner tried to follow every rule about providing information to surgeons. I don't think you're going to hear that he got anything wrong. But even if he did, getting a rule wrong is not fraud. It's not fraud on doctors; it's not fraud on the FDA; it is not fraud on anyone.

In closing, we have a long trial ahead of us. I think what the prosecutors are going to try to do in this case is throw a lot of stuff up against the wall and hope that

something sticks.

Keep an open mind. Witness testifying on direct examination and then cross-examination is coming up around the bend. And keep your eye on the ball. Just keep asking yourselves, where is the evidence of fraud?

Once you've heard all the evidence, reviewed it, thought about it, you are going to have no trouble concluding that Bill Heppner had no criminal intent, that he acted in complete good faith. The burden is on the government to prove criminal intent and lack of good faith beyond a reasonable doubt. And the government is not even going to come close for a very simple reason: Bill Heppner engaged in no fraud.

Thank you all.

THE COURT: Mr. Gurney?

MR. GURNEY: Thank you, your Honor.

May it please the Court, good afternoon, everyone. I know what you're thinking at this point. You're thinking this guy -- me -- is the one thing that stands between you and lunchtime. But I ask for your attention for a little bit longer. I'm not going to repeat everything that's been said already. But I'm going to make for you what I think are the essential points about Dave Ard.

Again, my name is Brent Gurney. And I represent Dave, along with my colleague, Miranda Hooker.

Dave, would you stand. Thank you.

It's my privilege and honor to represent Dave. Dave has been waiting for his day in court for several years now. Let me say this loud and clear: Dave is innocent of these charges. Dave is innocent of these charges. There is not going to be a shred of evidence to support the charges against Dave Ard. Everything about these charges is inconsistent with Dave, who he is, how he has lived his life, how he conducted himself when he was at Stryker Biotech. Dave always tried to do the right thing as he believed and understood it at all times. That is completely inconsistent with criminal intent.

Now, Dave is charged in just two counts -- excuse me -- with two things: conspiracy and wire fraud. The conspiracy charges Dave with a conspiracy to defraud the FDA. We've heard the word "fraud" a couple of times. What does that mean? It means to lie, to trick, to cheat. To deliberately mislead. That is a completely unfair allegation against Dave who, as you will see, had nothing to do with the FDA.

And the second half of that is that he conspired to commit wire fraud. And then he's charged in a separate set of counts with scheming to commit wire fraud. Conspiracy in a scheme to commit wire fraud. To establish a conspiracy, the government must prove first that there was a conspiracy, which is an illegal agreement, that two or more people got together and said, Let's commit a crime. Here cheating and tricking the FDA and surgeons.

And a scheme, a wire fraud scheme is the same thing. You have to show that there was a scheme. People got together and schemed. It wasn't like an accident or a single event. You got together and you schemed to commit wire fraud.

Both of those crimes require something else. They require criminal intent. The Judge will explain to you at the end of the case, they require proof of willfulness. That is the intent to commit a crime with a bad purpose: to disregard the law. Criminal intent. No intent, no crime.

The flip side of that is good faith is a complete defense to these charges: doing what you thought was right, making statements you believed were truthful, doing the best you could. That's good faith. Good faith is a complete defense to these charges: no intent, no crime, good faith, a complete defense.

Let me make one other comment about these charges. Dave is not charged with anything called misbranding or off-label promotion or anything like that. He's charged with these two very different charges: conspiracy and scheming. There isn't even a crime called mixing. There isn't a crime called off-label promotion. Dave is not charged with any such thing.

Now, I know what else you might be thinking or you may have been thinking when you came in the other day. Judge O'Toole told you how every criminal defendant is presumed

innocent. You learned that in grade school. But I know that some of you or maybe all of you might be thinking, because it's natural, you come into this nice big federal courtroom and there's a federal judge here and there's a mile-long table with all these lawyers and there's people in the back and it takes three days to select a jury, and you might be thinking to yourself, despite the presumption of innocent, Wow, somebody must have done something or we wouldn't be here.

You look around and you see Dave sitting over here, and maybe you're not presuming that he's innocent. That would be very, very dangerous. Of course, it would be wrong. It violates all of our constitutional principles and the Judge's instructions.

But putting that aside, it would be very dangerous for the following reasons. We can all think of situations in our personal experiences -- maybe with our families, maybe at work, maybe at school, maybe with our children -- where we rushed to judgment, and we didn't have the facts. Somebody rushed to judgment about us when they didn't have the facts. And we made false assumptions and false conclusions without evidence to back them up.

Dave is presumed innocent unless the government has evidence that proves him guilty beyond a reasonable doubt, and they do not have that evidence. The Judge mentioned before we started this morning that this case can be sort of like a

puzzle. And that's a wonderful analogy. It is like a puzzle. Each document, each witness is a piece of the puzzle. And you have to wait until you have all the pieces until you see what kind of a picture emerges.

In fact, it reminds me of a story that a friend told me about his two boys. They were playing with some puzzles one day down on the floor, they had them spread out, and he walked by and that was nice, they were occupied and not fighting. And he came back a little later, they had made a little progress on the puzzle. He looked at it, he said, That's nice.

And he passed by a little while later and he came back, and they had completed a little more of the puzzle and he looked down and he looked at the box nearby, the puzzle box, and what they were putting together didn't seem to quite really match up with the picture. Maybe they were doing it wrong. They're just little boys. But he wasn't going to say anything. Kids play. Let them figure it out.

And he came by later, and this time they had the whole puzzle completed. And he looked down and it definitely didn't match the box, the puzzle box. Because it was a completely different puzzle. They had a bunch of puzzles on the floor and they had a bunch of boxes. And the one he had been looking at and assuming went with this box did not. So he made a false assumption until the puzzle was completed.

That's what the government is doing here. They're

trying to take a bunch of puzzle pieces and put them together as best they can that do not add up to the sinister criminal picture that they're trying to convey. That is what the presumption of innocence is all about.

Who is Dave? Well, Dave's a family man. He's married to a lovely woman named Natalie who's here today. Natalie. She can't be here every day. They have three young children who are ages five, three, and a baby, ten months, so -- and they live in California. So she'll come when she can, but she can't be here all the time.

Dave comes from a close family of four. His father, now retired and disabled, was a sheriff. He worked his way through school. In high school he worked at a muffler factory and a printer -- he was a printer for a local union. He qualified for the United States Olympic trials in wrestling. He went on to the University of Sacramento where he also continued to work his way through school. He worked on a union crew at night loading trucks, and in the summers in the farmlands there hauling hay, another thing by truck.

Then after he graduated from the University of Sacramento, he held a series of jobs until about 1994-1995. He began selling medical devices for the first time for a company named OrthoLogic. He did that for several years. And in 2001 he started his own small business, which was a distributor of orthopedic products. And he built that business up, it was a

small business, but he built the business up, and it was relatively successful. And in 2005, he sold it. And shortly thereafter, he went to work at Stryker Biotech in August of 2005.

I'm a visual person, so I put this chart together to help me tell the story. In August of 2005, this is when Dave starts at Stryker Biotech. And I'll go over some of this other stuff in a moment. Why does he join Stryker? Well, he was excited about the opportunity, and in particular, he was excited about OP-1. You've already heard about it. Why? Because this product grows bone. This product grows bone. Think about that.

You know, we moved from putting broken bones in casts and splints. Now we have a product that grows bone. It helps the body heal itself. And that was -- was and is a wonderful product. And he thought it presented to him an exciting opportunity, for him and his career, for him and his family, on a long-term basis. And so he went to work at Stryker Biotech.

Stryker hired him specifically to be the regional sales manager in the West. They were very interested in Dave as being -- to take the position as regional sales manager because he already had strong relationships with surgeons in the western part of the United States.

You've already heard several people talk about how relationships with these very elite spine surgeons is

everything. Well, it is. These salespeople -- it's not like going door to door selling vacuums -- not that there's anything wrong with that -- but this depends on a long-term, deep, repeat relationship. That's the way that you grow professionally. And so they were interested in that.

They were also interested in his management experience. Remember, he had run this small business. So they thought he would be a good manager. So he came to work at Stryker in August of 2005, and he had about six sales reps as part of his territory out in the West. Now, he lived and worked out of his house in California. That's why I put a little picture of a house here. He lived and worked out of his house here in California, in Alamo, California. And Stryker is over here in Massachusetts. That's where headquarters is. That's where regulatory affairs is. That's where marketing and sales support, quality, the president, that's where the headquarters is.

He had very -- he made limited trips out here. He spent most of his time out here and worked out of his -- out of his home.

Now, you've heard about the launch of OP-1 Implant, Putty, and Calstrux. That all happened before Dave came to Stryker. The first one that was approved, OP-1 Implant, that's the one that goes into the long bones. That was approved back in 2001. OP-1 Putty, that's the one that goes into the spine,

that was approved in 2004. He wasn't at the company then. Calstrux, which you've heard about, that was approved in August of 2004. He still wasn't at the company. And then in August he comes to the company.

Now, one month after Dave joins the company, Stryker Biotech sent out their first Dear Doctor letter, which several have already talked about. What's a Dear Doctor letter? Well, it's a letter to doctors, it's an educational letter, reminding them of the instructions for the use of the products, discussing any issues that the surgeon should be aware of. This letter went to hundreds and hundreds of surgeons.

I don't really understand the allegation that the company was out to deceive surgeons when just one month after Dave arrived, the company is sending out letters to surgeons. That doesn't make any sense to me at all. But the real point here is just one month after Dave arrived -- he probably still hasn't gotten his security pass -- the company sends out this letter. He didn't have anything to do with it. This was all handled over here because he's the sales manager out there.

Then in February of 2006, there's another issue about whether they should send out a second Dear Doctor letter. And you heard how that was discussed at the highest levels of Stryker Biotech, and eventually they decided there were good and valid reasons why they didn't need to send it out right then, and they decided to send it out several months later.

And again, there doesn't seem to be anything wrong with that. But the important point here is Dave also had nothing to do with that.

There's very little about this case that has anything to do with Dave. That happened ultimately at the end of 2006.

You heard the government talk about a teleconference in March of 2006 concerning the rules on off-label promotion. The first thing I want to say is, the rules on off-label promotion are not what Dave is charged with in this conspiracy and scheming count, okay? The rules against off-label promotion are rules over here. Dave is charged with something completely separate: conspiring and scheming. When you hear the prosecutors talk, you might think sometimes there's some crime called off-label promotion.

Dave is not charged with any such thing. And violation of rules, policies, and procedures, while nobody intentionally sought to do that, has nothing to do with charges of conspiring and scheming. You know, we all have giant policy manuals where we work. Violating the rules and the policies and procedures, that's one thing. It's not conspiring and scheming.

But they have this conference in 2006, and the purpose of the conference was to reinforce the rules on off-label promotion and other purposes. Well, Dave knew and understood and believed in following the rules, and he -- to the extent

they're relevant at all -- and knew that it was inappropriate to promote products off label. And he did not do that. He followed those rules. And you'll see examples of him following and educating his own people on the rules. This whole conference -- I don't have it on my timeline here -- that occurs in March of 2006. Dave's only been at the company for about six months at that point.

Now, Dave also knew that while you can't promote off label, that surgeons often and frequently do use products off label. He knew that surgeons want information and ask questions about off-label uses. And he knew by law that the FDA cannot regulate or interfere with the practice of medicine. So doctors can use these products any way they want. Doctors, in order to practice and help their patients, often need information; and doctors often seek it from sales representatives.

Dave did the best he could to follow these rules as he understood them. And he did follow those rules. He did so in good faith. Remember, good faith is a complete defense: no intent, no crime. The government's theory here boils basically down to surgeons were tricked into using these products in some way they didn't otherwise want to use them. To believe in that theory, to accept that theory, you have to believe that these surgeons, these highly educated spine, brain, orthopedic surgeons with résumés as long as this table are too stupid to

know how to use products that they put in patients' bodies.

This may not be clear. There's really only two products out there in the bone-growing category: OP-1 and InFuse. So this isn't like going to the grocery store, and there's 400 brands of toothpaste with fluoride and cavity protection and all the rest, and you get confused which is which. There's only two bone-growing proteins out there.

A surgeon could not be easily confused about the indications of how to use these products. And certainly not these surgeons, which are among the elite of the elite.

Let's talk about what Dave was not. As I said, Dave was a sales manager in the Western Region, doing the best he could to help the people he worked with. That meant helping them form surgeon relationships like he had, helping them to grow the business, helping them with problems, setting standards.

Dave was not a regulatory specialist. He was not a lawyer. He had absolutely nothing to do with the FDA. He had nothing to do with FDA filings. He had nothing to do with reporting to the FDA or communicating with the FDA. The charge that he could possibly have defrauded the FDA in any way, shape, or form is preposterous.

Let's show -- let me talk about what the proof will not show against Dave. The proof will not show that Dave made a single false statement. And that is the essence of the

scheming and conspiracy charges: lying, tricking, deceiving, misleading. The evidence will not show that he made a single false statement. The evidence will not show a single instance of concealment on his part. Everything Dave did was in the open. No secret behavior, no scheming behind closed doors. He is not a conspirator; he is not a schemer. There's absolutely and will be no evidence that he sought to lie or trick or cheat a doctor.

In fact, as several said, that makes absolutely no sense whatsoever. You would come to a company because you're excited about the product and a long-term professional career at the company, and you would build your business plan on lying and cheating and tricking doctors? That makes no sense whatsoever.

There will be no evidence of willfulness or bad intent on Dave's part. Remember, no intent, no crime.

The government talked about adverse events. I believe a picture is worth a thousand words. Mr. O'Connor gave you some of the statistics. But I've tried to put it in a picture form to drive home the point. You will see and hear evidence that there are well over 10,000 uses of these products -- OP-1 and Calstrux -- used in combination, okay? Over 10,000. And to hear the government talk, you'd think that there would be an equal number of adverse events. That's not the case. There's just 63 potential adverse events reported out of over 10,000.

I want to pause on the word "potential," okay? Because although they call it an adverse event, what is an adverse event? An adverse event is any event -- any potentially bad experience that occurs during the use of a product. It could be inflammation, could be a headache. It could be anything.

But there's no requirement to establish causation when you report these things, all right? So we say "potential" because even -- these are all that were reported, but nobody has shown that these were even due to the use of the products. So "potential" is very important.

So out of over 10,000 uses, over several years, we just have 63 reports. Just 63. Less than one percent. Actually, 0.63, to be precise, okay? All right?

All products have adverse events. Baby aspirin can cause an adverse event. All products have some risk. The fact that there might be concern about preventing adverse events doesn't mean that the product is unsafe. In fact, these show that these products were extraordinarily safe, okay? And so Dave, to the extent he had any say whatsoever about adverse events or disclosing them, would have had no motive whatsoever to try and conceal these because there's really nothing to conceal.

As Mr. O'Connor told you, all of the potential -- all of the adverse events were warned about on the package labeling

and otherwise. That information was communicated up the wazoo by this company.

I listened very carefully to the government's opening, and I heard them throw around a lot of allegations. I heard them say only one specific thing about Dave. They said that he sent some mixing instructions, which are the basis for Count 5.

Now, remember, there's several counts in this wire fraud scheme that are charged. Only one of them is Dave doing anything. The government said he sent some mixing instructions. And it went by so fast maybe you didn't even catch it or maybe they didn't say, but the mixing instructions that he sent, he sent to another company employee, all right? They didn't go to a doctor. They didn't go to a surgeon. There wouldn't be anything wrong if they had gone to a surgeon because they weren't false.

I mean, these are just -- all they were are some instructions about how to mix. They weren't false any more than a recipe for making brownies could be false. You know, the recipe says put in the two eggs and a cup of oil and the mixture and you mix it up. The recipe can't be false. These are just instructions. But in any event, they didn't go to a surgeon. They went to an employee, somebody -- a member of the sales team.

Well, that is a big load of nothing. There's no crime, there's no false statement. They're just going

internally. And you will hear evidence that it's important to educate members -- employees so that they are appropriately prepared for when they are in surgeries. So there's a lot of internal education going on, sharing of information.

And yes, if an employee finds himself in the operating room and that surgeon has made the decision to mix -- the surgeon has made the decision to mix, as he is entitled to do under law -- and he turns to a sales rep in the OR and he says, Okay, give me the products. We're ready to do the implant, and he turns and he asks a question to the employee -- to the sales rep in the OR, who is there by the surgeon's invitation and many times demand, and he asks him a question, that sales rep better be prepared to answer it, okay?

These spine surgeons, again, they're among the elite of the elite. And in the OR, they are the captains of the ship. And everybody else is a deckhand, okay? And when they turn to the sales rep and they ask a question, the rep better be prepared to answer it or they are done with that surgeon, okay? So it's important that they be in a position to be able to do that.

Now, here's where the whole -- the government's case just totally blows up. In order for the government's case to work, you have to believe -- you really have to believe that these elite surgeons are just really stupid. You also have to believe that it was Dave's business plan to go out and lie and

trick doctors on a repeated basis, all right? That you would do this repeatedly. That's what a scheme and a conspiracy is all about. It's not just -- it's not run in, sell the vacuum, and run out.

This was all about long-term relationships, building a business, and bringing and promoting and selling this wonderful product: OP-1, okay? You lie or you trick a surgeon, the captain of the ship, you are dead. Your business is over. Relationships are everything. And that's where this case just blows up.

The government really has thrown the whole kitchen sink at Dave. It's trying to connect a bunch of dots that don't go together, that can't be connected. They're trying to put the puzzle pieces as best they can into a picture that just isn't there. There's not a shred of evidence that Dave tried to lie, cheat, or trick surgeons, the FDA, or anybody else. At the end of the evidence after you've seen all the puzzle pieces, the picture will be clear. And there will be only one verdict for Dave Ard. And the outcome will be very simple for you: Not guilty.

Thank you.

THE COURT: Jurors, we've reached 1:00 o'clock. We do have one further opening statement. We'll do that tomorrow morning.

MR. LIBBY: Thank you, your Honor.

THE COURT: We're going to try to keep to our schedule: 9:00 to 1:00, as I promised you, so you have other things to do.

Let me remind you, I urge you to remember my instructions to not discuss the substance of the matter either among yourselves or with anyone at home, and no independent investigation and so on. And again, if there are any press reports that you happen to stumble across, put them aside and don't pay attention. It's what you hear in the courtroom that matters.

With that, enjoy the rest of the day. It's a pretty miserable day, but do your best. And we'll see you tomorrow. We'll have the opening statement for Mr. Whitaker, and then we'll begin the evidence.

THE CLERK: All rise for the Court and the jury. The Court will be in recess.

(The Court and the jury exit the courtroom and the proceedings adjourned at 1:00 p.m.)

C E R T I F I C A T E

We, Marcia G. Patrisso, RMR, CRR, Official Reporter of the United States District Court, and Kimberly A. Smith, RDR, CRR, do hereby certify that the foregoing transcript constitutes, to the best of our skills and abilities, a true and accurate transcription of our stenotype notes taken in the matter of Criminal Action No. 09-10330-GAO, United States v. Stryker Biotech, et al.

/s/ Marcia G. Patrisso
MARCIA G. PATRISSO, RMR, CRR
Official Court Reporter

/s/ Kimberly A. Smith
KIMBERLY A. SMITH, RDR, CRR

Date: January 12, 2012